

AT

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FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

PUBLIC MEETING:

**PROPOSED CHANGES
TO THE NATIONAL DRUG CODE (NDC) SYSTEM**

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9 o'clock a.m.

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P R O C E E D I N G S**Opening Remarks**

MR. BERNSTEIN: I'm Michael Bernstein. I am the Director of the Division of Regulatory Policy II in the Office of Regulatory Policy in CDER. I will be moderating today's meeting on the National Drug Code System.

As you all know, FDA published its electronic drug registration and listing proposed rule at the end of August and we recently extended the comment period to January 26th. We also announced that we would hold this public meeting on the NDC Code topic.

The purpose of this meeting is to solicit public input on the proposed changes to the National Drug Code system that is contained in that proposed rule. We have a large number of speakers who have requested time today and time is limited, as I said, so please try to limit yourself to the allotted time on the agendas that I think have circulated. If, after you are introduced, you could state your name and affiliation and move

right to your presentation, that would be appreciated.

We also have a panel of FDA staffers and a representative from CMS. They are largely going to listen today although they may ask some questions of presenters. But we are going to try to keep those questions limited to clarification questions.

The role of FDA here today is to listen to the speakers and consider your concerns and your viewpoints on issues relating to the National Drug Code system. So please don't expect to hear guidance, substantive guidance, from the panelists.

We have also tried to schedule some time for audience comments and participation at the end of both sessions. Time permitting, we will do that. There will be two microphones.

Before we get to the presentations, Dr. John Gardner, of the Office of Compliance, is going to open the meeting with a very brief overview of the electronic drug registration and listing proposal on the NDC issues and review the specific discussion topics very briefly that were raised in

the meeting notice.

After that, we will introduce the panel and then we will get right to the public presentations. So, without further ado, Dr. Gardner?

Overview

DR. GARDNER: Good morning. I wanted to briefly give you an overview of what we are trying to propose and where we are going in terms of electronic drug registration and listing. I want to emphasize that where we are going is very flexible. We are not moving forward with anything definitive until we are through reviewing all the comments that have come in on the proposed rule and that resolve a lot of the issues that are raised there.

So the rule, itself, really has five major components that are changes. The first is that there is electronic submission of the registration listing information. We are developing two systems to do that, one for electronic registration, which we call the Drug Facility Registration Module,

which is a component of the FDA Uniform Registration and Listing System.

The second is a program we call eLIST which has been formulated and is about to be developed.

The second piece is electronic submission of the content of labeling. That is already a requirement for application prescription drugs. This rule would extend that requirement to all drugs that the content of labeling, what we call the structured product labeling (SPL), would be required to be submitted electronically.

The third change is that FDA would issue the complete NDC number, not just the labeler code as we currently do. I will talk to you a little bit more about that later. The NDC directory will then become the public posting of all FDA-issued NDC numbers and that will be coordinated with the DailyMed website.

The fourth change is that the NDC number will be required to be printed on product labels. That requirement is proposed to be the appropriate

NDC number which is the last firm which has handled the product--that is, changed the product.

Let me now clarify the difference between a drug and drug product. A drug is, for example ampicillin. A drug product example ampicillin, 250 milligram tablets made by a specific company and marketed by a specific company in bottles of 30. Each drug product has a unique NDC number and there are often many, and sometimes, hundreds of NDC numbers for each drug.

This product would have to have the NDC number printed on it and the reason, our thinking on why it has to be the most recent, is so that we can trace that back from the private-label distributor to the relabeler, to the repacker, to the manufacturer so we can deal with specific product issues.

Then, finally, the final change proposed is that firms must recertify their listing information every six months. Currently, they have to update their information in June and December if it has changed, then this would require that they

come in and certify that it has not changed or change it if it has changed.

So those are the five major components of the proposed rule. I want to now talk to you about our drug registration listing system. This program comes under my division in the Office of Compliance.

Drug-establishment registration and drug-product listing was enacted to protect the public from adulterated and misbranded drugs. Drug establishments must register annually to provide contact and location information. Firms must list each of their drug products that are being marketed in the United States, giving names and ingredients, et cetera.

We use these data in the system for many purposes. I think it is central to almost everything we do, being able to identify the drug products. It is the repository of NDC numbers. Registration currently provides, and in the future would provide, the labeler component of the NDC. Registration gives us location and contact

information so that we can identify who is making drugs and it identifies sites for inspection.

Listing provides the manufacturing information, ingredients information, for marketed drugs. It helps us to identify violative drug products. It assists with control of drug imports.

The electronic system will support the SPL DailyMed initiative. Its key role is to provide linkage of a drug product, a specific drug product, with the labeling, with the approval status, with the marketer and with the manufacturer so that we can know each of these components related to each specific drug product.

It helps counterterrorism, supports our FDA safety databases by, again, linking the specific products to the issues, helps us in drug shortages. We have used it frequently to identify products containing an ingredient is being recalled; we use this system to identify the manufacturers and the products that are out there that have that ingredient.

In Hurricane Katrina, we were one of the

first people who were called, saying, "What firms might be impacted by the hurricane? Is that a problem we need to worry about in terms of drug supply and shortages?" and so on.

We also have the repository of drug-product labeling which currently is in paper system but, under the proposed rule, we would make electronic.

The NDC is also used in drug billing and reimbursement. The Centers for Medicaid and Medicare Services use our information to determine drug eligibility for their rebate and reimbursement programs. The NDC directory is widely used for lots of reasons. Nearly all pharmacy billing systems and reimbursement systems use the NDC. So we think it is extremely important to keep that information complete and accurate.

The history started way back in the '70s, a paper system. Our current Oracle system was developed in 1991 and we are now developing the new electronic system with the two components that I mentioned.

We have about 25,000 active facilities registered. We are estimating approximately 200,000 specific drug products on the market. We do not have all of those in our electronic system.

Due to resource limitations, part of those are still in paper systems. One of the reasons for this rule is to change that and get everything electronic.

We spent a lot of money processing about 10,000 registration forms and 30,000 listing forms each year. Just the data-entry process, itself, is nearly a million dollars a year that we are struggling to maintain. Because of limitations, we haven't been able to maintain everything in the electronic system.

This slide provides a list for you of the information we have for each firm and each manufacturer and of the products and the functions related to those product. You can read these on the slides when we post them.

In the future, we are already moving toward an electronic drug registration and listing

system. We would provide the electronic submission on an on-line basis for registration and, as I will mention, through submission of electronic labeling for drug-product listing, this will greatly improve the accuracy and completeness of our system, minimize data-input requirements (I think both for us and for industry), and allow more focus on the safety and regulatory issues.

Our plans are to implement these new features of registration listing and, in the process, implement partially automated validation of the listings so that we can avoid a lot of the manual review that would be necessary otherwise.

First, let me talk about drug-establishment registration. This is already in the works. Our system is already partially developed and implemented internally, the drug-facility registration module (DFRM). We will soon be providing access for industry so that industry will be able to get an account in FURLS, log in to DFRM and then enter and/or update their registration electronically. All paper forms will

eventually be eliminated and annual updating will be greatly simplified. I will show you that in just a minute.

This will be the central system through FURLS that will be the master inventory of drug establishments and their official contact and importer information.

This is a screen shot of FURLS, with hypothetical data. Basically, as you enter, you go through an eight-step process that takes about ten minutes if you have the information ready. When you update, you will go back and pull up the information that is already there through this process shown on the slide.

As you see here, you just scroll down through the page. You get to Section 1. You look at it. If you have changes, you click the edit button that takes you to this section to do the editing. Section 1 gives you the type of registration and the type of facility and your registration number. It will be controlled by a password system so that only you will be able to

access it.

Then you get to Section 2 which gives the name, address and so on. Then you get to Section 3 which goes through your preferred contacts and contact, address. Then you go to Section 4 which gives your parent-company information. Section 5 is your official contact information and section 6 is trade names.

Section 7 is your U.S. agent information if you are a foreign firm. Then Sections 8, 9 and 10, I didn't give you slides of, but they are importers in Section 8. Section 9 is the type of activities conducted in the facility and Section 10 is a certification statement.

So let me move from registration toward listing. I'm presenting the way we are designing Listing, and our current thinking is to run this using structured product labeling that is, your electronic product label. The electronic SPL requirement in XML format is already in place for the content of labeling for application prescription drugs. It allows electronic edit,

search, review, and archiving of drug labeling. That drug labeling is the prescriber package insert or the content of labeling, as we define it.

In October of last year (2005), industry started providing SPL for application human prescription drugs and, through their annual reports, should have submitted all of those by now.

Those are being processed and posted, once their processing is complete, at the National Library of Medicine's DailyMed website. You can go to that website and see the information there that gives you the entire content of labeling.

Of most interest right now is, at the end, you will see a table, a data table. That data table is basically the listing information. So our proposed eLIST system will capture that data table and utilize that for electronic drug listing.

So this listing information and the SPL information will all integrate eventually with electronic prescribing and public drug information access programs.

So our eLIST system is being designed

around these SPL submissions and will extract the coded data elements from the SPL and then, for the small amount of information that is not in the product labeling, industry will log in, through FURLS, and add that additional information.

Then the system we are developing will electronically validate as much of the listing information as possible including the structure and format of the NDC number. Our current thinking is that we will have the SPL submitted with the company's proposed NDC number on it. It will validate and verify that it meets the required rules--that is, the format and the structure.

The labeler code has to be the right labeler code. The product code has to be the same for the same product and different for a different product, and so on. Then, if it validates the format and structure, it will be accepted and the company immediately notified that that NDC number is accepted.

It will not be legal NDC number until the entire drug-approval and listing process is

complete. Once that is done, then it will be issued--that same number will be issued and posted in the NDC Directory and the DailyMed website along with electronic labeling and other FDA information systems.

eLIST will also electronically validate that that drug has been approved or that the OTC Monograph requirements have been met and then also we will check on the labeling approval. Once that is completed then, as I mentioned, all this will be posted.

So this system is designed to greatly facilitate drug listing both for industry and for us and it will improve the accuracy and completeness of the information. It will eliminate having to enter information twice. You do it once on your drug label and never have to do it again.

Every time you change your drug label, you resubmit that to FDA and it will automatically validate through the same process again. Parts of the process may require manual validation. Those may take a little bit longer, but the automated

validation components will happen immediately.

The validation will have to be implemented so we maintain flexibility. Our current thinking is that the validation would verify that the NDA is approved, or ANDA, or that the product meets the over-the-counter drug monograph requirements if it is an over-the-counter drug without an NDA.

This year, we recalled two brands of vapor patches, over-the-counter vapor patches. These companies really should have been notified at the time they listed the products that these require an NDA, as do all extended-release products, for example. So if the system automatically determined that you have an extended-released product without an NDA, then you would get a notification back that this requires an NDA to be legally marketed.

It would also provide the accurate linkage with the NDC Directory, with FDA's drug-information systems, and tie together everything we have about drugs and link them specifically to those individual unique drug products.

This is all a part of a larger program

whose goals are to provide accessible electronic medication information--DailyMed is a big piece of that--and eventually to provide for electronic drug prescribing and, secondly, to provide accurate identification of drug products and biologic products on the market.

This goes back to the electronic labeling rule which applies to application prescription drugs. It goes back to the Physician Labeling Rule which prescribes the format of that electronic label. Then this is the drug listing rule. Through this process of information collection, the manufacturers, repackers, relabelers, submit the types of information and the data coding of that information, the electronic listing and medication information comes forward.

The drug labels (the SPLs) are processed through a program called ELIPS, where they are reviewed, edited and approved. The electronic listing would be processed through eLIST. Once all of this validation and quality control is determined, then they become public and are made

publicly available in standardized form to populate standardized electronic data systems such as DailyMed which then could be downloaded to use as a source for other information systems.

This illustrates this listing process for application drugs that have their SPL submitted through the application process. That information will be captured through this listing system. The NDC will be pulled and validated and that can happen as soon as the labels have been submitted at any time, even with a preliminary label being submitted. Then the validation of the approval status goes through the NDA or ANDA process. For drugs that don't go through that process we will have some electronic validation of labeling structure, format and, perhaps, content, to the extent we can do it electronically. But some of that will have to be done manually. What I was talking about there is non application drugs with SPL. Then you have certain categories of drugs without SPL, like bulk ingredients, that would come in. We would have a system there for them to enter

that information or submit in XML or a to-be-specified format.

Then you have the repacker, relabelers, who would come in with their products. They simply have to submit the NDC number of the listed product. If they have a properly listed product, they simply submit that NDC number and then we pull the information from that listed product and they would add what they need to change this to the drug labeling, like the name and how supplied section. Then their SPL would be created for them.

Again, the NDCs that they submit will all be validated. The listing and labeling information would be validated. Then those would be posted to FDA and NLM sites for access electronically to the healthcare community.

The other piece of this is to go in and update information and the semi-annual certification. Our thinking, at present, is that, since the law says June and December, on June 1, you would get an e-mail that says, here is your product that needs to be updated.

You click a button on that e-mail. It brings you right to the certification statement where you review your information. Then you can review your information and update at that time.

That is another piece I didn't mention. Part of the electronic submission proposed rule requires e-mail addresses and fax numbers, which are not in the current regulation.

So that is really an overview of our thinking and where we are trying to go with electronic registration and listing.

Now I want to talk just a little bit about the scope of the meeting. We are holding this meeting to get comment on the NDC issues related to the proposed rule. We have listed a few of them that are major points. The rule is open for comment until January 26th. At this meeting, we are trying to limit our discussion to the NDC-related issues.

One is that the NDC number is printed on the product label and that it be the appropriate NDC number of the last firm handling the product.

Again, that is for the public-health purpose of being able to trace the specific product back to the original manufacturer.

The format of the printed NDC number--that is, it will be preceded by an "NDC". The example I have given here is not a current legal NDC. But I put it up this way because this is how we carry it in our database. We carry it in our database as three separate fields, the labeler code, the product code and the package code. Under current regulations, that has to collapse to 10 digits by using a 5-4-1 or 5-3-2 or 4-4-2 configuration. That collapsing, then, causes a lot of confusion. So, in the bottom bullet, we are requesting comment on the impact of expanding to 11 digits which, I believe, is the Medicare-Medicaid standard.

We felt like we are constrained to 10 digits because of barcode issues. But, if that is not the case, I think it might be better for everyone if we go to 11 digits. We would like to hear comment on that issue.

The second point is that FDA assigns and

issues the full NDC number and we feel that that is critically important to do in order to control the use of these NDC numbers and make sure that they are formatted properly. Again, with the automated validation, we would then be able to inform firms immediately of product requirements they may not have been aware of, such as they require a new drug application or they are not compliant with the OTC monograph, and so on. Again, we would publish, in the NDC Directory, the listing of all legal or valid FDA-issued NDC numbers.

The third point is NDC number use and restrictions; that is, the product code must change if the product changes, if the formulation changes or the manufacturer changes. That, again, is identifying unique products.

I know there is an issue with inactive ingredients but there are certain inactive ingredients that some patients are allergic to, and so on. So we need to be able to identify those products that have different inactive ingredients as different products and, therefore, different NDC

numbers.

The NDC number must be the same if it is the same formulation and manufacturer or if you discontinue a product and reintroduce that product without change, then it has to be the same NDC number and not a new one. Also, you can't use the same NDC number for different products. I think that is a necessary part of uniquely identifying each drug product on the market.

Finally, that it is not used for non-drugs. I know there are concerns here about reimbursement issues. We have no role in reimbursement, but we do want to assure that reimbursement systems understand which products are drugs and which are not. Non-drugs do not have NDC numbers. So devices or human foods that are not considered drugs by FDA then would be reimbursed under their appropriate device or other category, rather than as drugs.

We have worked with the Centers for Medicaid and Medicare Services over the last several years to remove thousands of products from

their drug reimbursement system because they are medical devices or human dietary supplements.

There is tremendous confusion because the initial assumption is always that, if a product has an NDC number, then it is a drug. That has not been the case, but we think inappropriately so. So we want to fix that in this rule. So we would appreciate having comment on that issue as well.

Fourth, another issue is the NDC chain; that is the chain of NDC numbers from the private-label distributor's product back to the relabeled product back to the repackaged product back to the manufacturer. It is currently proposed that this chain be confidential because it might violate some proprietary business information.

So we, at FDA, would be able to be able to trace back every product, but the public wouldn't.

Whether we should make that publicly available is an issue we would like to hear comment on because we feel that, for public-health purposes, it might be appropriate to make that information public.

Finally, we have already talked about the

configuration of the NDC. We are not proposing changing the basic configuration of the NDC number--that is labeler code, product code and package code, but rather that we make the format consistent for all drugs. If we could go to eleven digits it might eliminate confusion, if it doesn't cause a lot of problems. So we would like to hear comment on that issue.

That is all I have. I will turn the time back to Michael.

MR. BERNSTEIN: Thank you, John.

Introduction of the Panel

MR. BERNSTEIN: At this point, I just want to introduce the panel. Before I do that, I wanted to give some thanks, I don't know if any of you have ever been involved in the planning for a meeting like this, but there are an incredible number of details and things that need to be taken care of to make sure that things run smoothly.

I just wanted to extend special thanks to Lakshmi Cherukuri in the Office of Compliance who, among many other people, worked exceptionally hard

to put all the details together so everything is functioning today, so the microphones are working and everything else. Thank you, Lakshmi, and all of your co-workers.

The panel today; you just heard from John Gardner. He is the Director of the Division of Compliance of Risk Management and Surveillance in the Office of Compliance at CDER. Also on my left is Dr. Randy Levin. He is the Director for Health and Regulatory Data Standards and the Associate Director of Medical Informatics for CDER.

To his left is Judith Geisler. She is the Acting Director of the Division of Finance and Operations in the Centers for Medicare and Medicaid Services. On my right is Anita Richardson, the Associate Director for Policy in the Office of Compliance and Biologics Quality in CBER and Charise Kasser who is a consumer safety officer in the Division of Surveillance in the Center for Veterinary Medicine, also on my right.

With that, again, if I forgot to say it in my initial remarks, I invite the registered

speakers on the agenda to come up to the podium and speak from here.

The first speaker is Kay Morgan with the National Council for Prescription Drug Programs, NCPDP.

Public Speakers

MS. MORGAN: Good morning. My name is Kay Morgan. I am here representing the National Council of Prescription Drug Programs or also known as NCPDP on this NPRM regarding the NDC numbers. Currently, I am an NCPDP Workgroup 2 Product Identification Co-Chair and I have formerly served as a member of the NCPDP Board of Trustees.

My fellow Co-Chairs, Ann Johnston of Medco and John Klimek of SuperValu, as well as Lynne Gilbertson, the Director of Standards Development for NCPDP are in attendance with me.

In addition to my NCPDP role, my professional responsibilities include the population of a drug database with information including the NDC number. I have previously been responsible for the population of similar data that

include NDCs and to two other databases.

NCPDP is a nonprofit ANSI-accredited standards development organization consisting of more than 1300 members who represent computer companies, drug manufacturers, pharmacy chains, independent pharmacies, drug wholesalers, insurers, mail-order, prescription-drug companies, telecommunication vendors, prescription-drug provider softwares, physician services, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the healthcare industry.

NCPDP has sent a written response to the FDA regarding this NPRM. My statements will speak to and highlight the NCPDP written response. The response was created through NCPDP's process of a task group which is open to all interested parties.

They create the initial recommendations for the letter. The task group consisted of participants from different sectors of the pharmacy-services industry. The letter was then

reviewed during an NCPDP November work group meeting and, again, by different sectors of the pharmacy-services industry and then was approved by the NCPDP Board of Trustees.

The NCPDP comments are: according to its interpretation of NPRM, NCPDP applauds the recommendation to disallow re-use of an NDC number once it is discontinued. Additionally, NCPDP highly approves the retention of the basic core NDC enumeration system, the requirement of a new NDC when a physical change is made and when an inactive ingredient change is made.

It is our understanding that the NDC will be part of the SPL initiative; as such, the inclusion of the product image from the manufacturer as part of the NDC listing would further enhance patient safety. Keeping this current system will prevent the disruption in the electronic exchange of information that occurs today between patients, pharmacies, processors, insurers and suppliers.

Disallowing the re-use of an NDC and

requiring a new NDC when there is a significant change to a product will prevent the confusion that occurs in today's market when an NDC is re-used. Data for the product that was represented by the NDC must be stored off and saved so as to not conflict with the new information for the new product.

When attributes of a product change without an NDC change, many databases simply overlay the old information with the new information as there is no other option and the old product may still be in the marketplace. This causes much confusion for the pharmacy and the patient.

Regarding the bar-code questions, NCPDP is very pleased to see that this rule allows for the barcode to be continued as part of the label. NCPDP encourages the use of the barcode to be used for the container labeling as well as on the packaging labeling. Barcoding of products has been used to help correctly identify that the right product is being dispensed. It is vital to many

quality-assurance systems and pharmacies and to patient safety so the product being administered can be verified as the correct product.

Regarding the National Drug Code question.

NCPDP agrees with this restriction cited for the use of the NDC number. Having seen inappropriately assigned NDCs, we support the FDA oversight of NDC assignment. In this rapid changing medication environment, the assignment must occur quickly.

NCPDP also agrees with the requirements for the electronic submission of the NDC so that the process can occur rapidly and it will minimize errors in transcription. Regarding the other postmarketing reports, NCPDP supports this requirement that the list remain current with actively marketed products and would encourage the FDA to use their existing posting processes, their listservs, to provide notification of change to the NDC listing. Additionally, NCPDP encourages the FDA to apply the same requirements to products listed in Part 330 human drugs which are generally recognized as safe and effective and not misbranded

and to products listed in Part 610, general biological products standards.

Regarding the general conditions for general recognition of safe, effective and not misbranded, NCPDP agrees with the listing of these products.

Regarding Part 601, the licensing of biologics, NCPDP supports the requirement for applications for biologics licenses procedures for filing that the list remains current with actively marketed products and would, again, encourage the FDA to use their existing posting processes such as the listserv to provide notifications of changes to the NDC listing.

Thank you for the opportunity to present for NCPDP.

MR. BERNSTEIN: Do any of the panelists have any follow up questions for Kay?

If not, our next speaker is John Coster, Vice President, Policy and Programs, for the National Association of Chain Drug Stores.

DR. COSTER: Thank you very much. I am

John Koster, Vice President of Policy and Programs with the National Association of Chain Drug Stores.

I am pleased to present comments today at this public hearing regarding FDA's proposals to change the way that NDC numbers are used. We are a trade association of approximately 188 companies representing about 35,000 community-based retail pharmacies. We appreciate the opportunity for the public hearing and the extension of the deadline for submission of comments given all the other rulemaking things going on in the world today.

Our members include small and large chain-operated pharmacies including traditional chain drugstores, supermarkets and mass merchandise pharmacies. We are the largest provider of outpatient retail prescriptions. We provide about 70 percent of the approximately 3.1 billion prescriptions dispensed. But changes to the NDC numbers affect our industry and independent pharmacies as well which are about, collectively, 55,000 pharmacies. We will both be impacted by these changes.

As you will probably hear throughout the day today, the entire system, all the way from the manufacturer to the wholesaler to the payer uses the NDC number. I will list these; to order, track, warehouse, account, distribute, prescribe, dispense, bill, reconcile payment and perform clinical functions on prescription drugs and healthcare products. So changes to this system, obviously, depending upon what they are, have an impact up and down the line. No system is perfect, but NDC scheme is working and has worked well to date.

NDC changes affect our industry in many ways. Our entire business model, as I said, is our ability to provide safe and effective pharmaceutical care to patients. It affects us as purchasers of repackaged drugs, as sellers of medical equipment and supplies such as diabetic testing supplies, as private-label distributors of over-the-counter drugs. Many of our members have their own private-label brands and many of our members also warehouse their own drugs as well.

My colleague from SuperValu, John Klimek, will discuss some of the operational issues of the changes. I wanted to focus my remarks on a particular part of the rule, specifically as it relates to the requirement that repackagers place their own NDC number on the drugs that they repackage.

This is a change in policy that concerns our industry as it relates specifically to the repackaged drugs that we purchase and use in our own pharmacies.

In summary, what we would like to ask is that the agency consider, in the final regulation, that the current exemption that it has generously provided to a specific class of repackagers--that is retail pharmacy service repackagers--be allowed to continue under the final rule when the rule was made final.

This exemption has allowed these repackagers to place the originator manufacturer's number, the NDC number of the originator manufacturer, on the packaged product rather than

their own NDC number.

It is critical for several reasons. Based on long-standing FDA guidance and universal commercial practice, the retail pharmacies' supply dispensing payment and reimbursement systems currently rely on the use of the original manufacturer's NDC number for branded single-source drugs.

We are not asking the agency to grant a broad exemption for all repackagers from the requirement that they use their own NDC because most repackagers, in our view, are acting more like manufacturers than they are traditional retail pharmacy service repackagers. We are only asking that the agency continue this narrow exemption that it has provided to date for retail pharmacy service repackagers for a limited number of drugs.

The services that these repackagers provide us are invaluable. They help enhance efficiency in the retail pharmacy marketplace and enhance patient safety. If these repackagers were to go away, as we think is possible under the rule

as proposed, they would be eliminated and that would have patient safety implications.

The repackaging of drugs for retail pharmacy distribution, in our view, is different from other repackaging. All this repackaging is simply repackaging activities by pharmacists from hundreds of individual or thousands of retail pharmacies to a single efficient operation that repackages drugs into quantities that are typically dispensed to patients by these same pharmacies.

While this type of repackaging is done for efficiency reasons, it often also provides important patient safety benefits. Rather than having repackaging occur in hundreds of thousands of different pharmacy sites, the central retail service repackager operation reduces costs, reduces the potential for pharmacy-based repackaging errors and reduces the amount of time that the pharmacy needs to be involved in repackaging medications rather than interacting with patients.

Retail pharmacy computer systems use the original manufacturer's NDC number to determine

what product is identified for dispensing purposes.

At this time, in the retail-pharmacy setting, the repackager NDC numbers are not used. In fact, many of them do not have their own. But retail-pharmacy service repackagers do not have their own NDC numbers.

For them to be used in the retail-pharmacy systems, each would have to be assigned a number. The number would have to be maintained by the repackagers and recognized by different database companies, PBMs, insurance companies, Medicaid and pharmacy software systems. Introduction of multiple repackagers into the marketplace for which no reimbursement metrics exist, such as AWP, WAC or AMP, would create significant disruption in the pharmacy supply chain.

Mandatory use of repackager NDC numbers, the retail-service repackager NDC numbers, will also place a significant burden on retail repackagers due to the Medicaid drug rebate requirements under Section 1927 of the Social Security Act. Because State Medicaid payments and

calculations are linked to NDC numbers, repackagers would be newly obliged to pay a substantial rebate fee at a statutory minimum of 15.1 percent of the AMP. This fact alone could eliminate these repackagers in the marketplace.

It is also likely that changes in the FDA policy will create complications in accurate billing and rebate collections for states.

In summary, we ask, for the reasons mentioned, that the FDA in its final rule allow for a continuation of its current policy that allows a small number of retail-pharmacy service repackagers to continue to place the original manufacturer's number of the repackaged product rather than their own.

We appreciate your consideration of this request.

MR. BERNSTEIN: Any questions from the panel? Thank you. Next up is John Klimek, the Manager of RxView SuperValu.

MR. KLIMEK: Good morning. My name is John Klimek. I work for SuperValu Pharmacies in

the capacity of managed care, third-party billing and pre- and post-editing of pharmacy claims using an internal application.

Thank you for the ability to speak in front of you this morning on the proposed rule for NDC number. In response to the agency assignment of NDC, pharmacies today depend on the integrity, intelligence of the NDC. We applaud the FDA's efforts in assuring that integrity remains intact.

Additionally, we approve the continuation of the core NDC enumeration system. With the advent of Medicare Part D, pharmacy billing for prescription and non-prescription DMA products accounts for over 90 percent of pharmacies' daily business.

Therefore, it is very important that pharmacies continue to rely on the intelligence with the NDC for identification and billing.

Today, we use and depend on each component of the NDC number; the labeler, product and package code. Depending on these individual codes helps pharmacies and other entities develop formulary inclusions/exclusions and drug-utilization review.

Also, when product FDA recalls are sent from the FDA and it usually involves one labeler and product code and all package sizes, we often use a wild card for the package code to be certain we are in compliance with that recall information.

Systems in some cases use general drug identifiers such as GCN, generic code number or GPI, generic product identifier, to program for categories of drugs. But, it is the structure of NDC number that gives specificity down to the product and manufacturer level.

The NDC touches many integral pharmacy systems. Any change to the expected 10-digit NDC format will have far-reaching effects both financially to those company systems as well as potential patient safety consequences.

Some examples of pharmacy systems that rely on the current 10-digit NDC structure are the pharmacy-prescription system for fill and refill, drug-file data, drug interactions, drug-allergy and patient-counseling information, drug-order information, prescriptions on file, pricing

formulas, third-party billing and reconciliation, transaction history reports, reports such as DEA reports, customer-profile reports, drug-utilization reports, customer-encounter reports, compliance reports, and so on.

In response to new NDC number when change of inactive ingredient, we support the proposal in a rule that would require that a new NDC of drug products would change when certain changes are made in the composition of the drug product such as active ingredients.

We have seen many situations in which a manufacturer has changed the active ingredient--of the ingredients but has neither changed the NDC number nor changed the name of the drug. We agree that the NDC number of marketed prescription-drug products should change when active ingredients change. However, we urge the agency to consider whether the number of potential modifications listed in the proposed rule would require an NDC-number change.

While we agree the NDC numbers should

identify unique products and packaging, we are concerned that it may be difficult to keep up with all the NDC changes from a pharmacy system in operational perspective. These concerns also filter into patient-safety implications.

The NDC is in most, if not all, pharmacy systems and prescription data is key indicator. If an NDC number changes on a standing prescription order, for whatever reason, it forces that pharmacy to rewrite that prescription in assigning a new prescription number. Doing so often causes confusion with the patient and sometimes the physician.

In response to dietary supplements and medical devices, many dietary supplements and medical devices are billed each and every day for many Medicaid and Medicare patients along with other private payers. Each of these products today have either a UPC or an NDC number. Pharmacies bill using either the true NDC number or, in some cases, of the UPC, they use that number to format it to and NDC number.

CPDP has developed a standard way to convert the UPC to an 11-digit NDC format that is used for billing purposes. This standard process is recognized and used by all major drug compendia such as MediSpan and First Data Bank.

Because of the potential impact on billing for these products, any discontinuation of a true NDC number will have significant impact on the manufacturers of these products along with possible disruption in supplying these products to our patients. Consequently, any changes should be allowed sufficient lead time to prevent interruption in servicing our patients.

Thank you.

MR. BERNSTEIN: Any questions for the speaker?

MR. LEVIN: Yes; I have a question. You were mentioning about the support to changes for the active ingredients. You said about the other components that might--what components would you now advocate a change?

MR. KLIMEK; There are some situations

like when inactive ingredients would change. We agree with the FDA that the NDC number should change but there are other components of that listing that could change which may not require the NDC to change.

MR. LEVIN: Like an example of that?

MR. KLIMEK: Whatever is listed, whatever is required for the listing of the NDC number. I am trying to think off the top of my head.

DR. GARDNER: The inactive ingredients.

MR. KLIMEK: Right.

MR. LEVIN: And then for the dietary supplements, it would have an impact if the NDCs were--

MR. KLIMEK: If there is no UPC--well, in most cases, where those prices are either to HRI or UPC numbers which pharmacies today will format that to an NDC number to bill. So we really have no issue with that as long as there is a product identifier that we can bill using that code.

DR. GARDNER: Would you talk a little more about the 10-digit--you mentioned the 11-digit

standard for NCPDP, but then you also talked about the need for the 10-digit version.

MR. KLIMEK: Again, which we had mentioned earlier, Dr. Gardner, was about the 10-digit number being out there. We basically take that 10-digit and format it to 11 digits.

DR. GARDNER: So if we started with an 11-digit number, you don't think that would cause a lot of disruption?

MR. KLIMEK: Our system handles 11 digits for the NDC number. I don't really see where that would cause us an issue.

DR. GARDNER: You mentioned drug interaction or other databases that do use 10-digit, but they convert to 11?

MR. KLIMEK: Right. All systems convert to 11.

DR. GARDNER: They all convert to 11?

MR. KLIMEK: Right.

DR. GARDNER: Okay. If we could convert to 11, I think we would like to because I think that would simplify everything for everyone. But

we need to know whether it will cause problems.

MR. KLIMEK: Right. It is our thought that if it goes anything beyond 11 digits that certainly would cause more issues as far as our database holding that large a field and, also, then, relating back the original processing.

DR. GARDNER: Thank you.

MR. BERNSTEIN: Next up is John Roberts.

MR. ROBERTS: Good morning, everyone. I am the third John in a row you may have noticed. I am going to wake you up now. I am the barcode person. UPC is owned by GS1. It is our standard. Going from a 10-digit to an 11-digit NDC will cause us great problems, great problems, indeed. I will get into that.

Our formal comments will be coming before January 26th. I am a staffer with GS1 US, a director of healthcare. Normally our healthcare user group will put together the comments and reply to the FDA from a global perspective.

I am glad that John gave the historical perspective of where the NDC came from. The UPC

came at the same time, roughly in the early '70s. The world has really changed since then, the National Drug Code and UPC. Those of you--I don't see a whole lot of grey hair, but there was a time when we didn't have barcodes on products at all. That started in the early '70s. Now, 30 years later, 40 years later, there is barcode on everything.

These things went on products in the early '60s and '70s. They were embedded into our symbols at that time, embedded into our entire system and it carried forward. The U.S. is the only country where we allow a specific drug number to be coded into our system.

Today, we are heavily integrated with global manufacturers and distribution. We are looking for non-standard applications, especially in healthcare, that really threaten the flow of products information and raise potential error. If the FDA wants to go to the 11-digit NDC, that is completely up to you, within your regulation.

However, we think you should decouple it

from putting in the barcode. What do I mean by that? There is no reason an NDC should be in a barcode. You could use a G-10 global-traded item number, instead, that is used everywhere that could be passed back and forth.

If the FDA changes the NDC from 10 to 11, it will cause serious disruptions to our entire system. We suggest, instead, that you delink it and use as a primary identification a global-traded item number. Most of us, because of the holiday season, went to the store over the weekend. Lots of UPCs were scanned. How many of you know what numbers were on them? None of you. I don't even look at the ones on there, but you know what product you bought because it showed up on the computer.

The G-10 points to the computer record that pops up what the item is. There is no reason for an NDC to be in there. A G-10 works quite well.

You can remove the NDC requirement in the barcode, use a G-10. The companies that are drug

companies already have G-10s on other products. If you don't like this solution, you might the NDC in secondary information. We have primary information which is the G-10, the product, the data structure that is in the barcode, secondary information like lot expiration date could be an NDC in there. It could be an application identifier. We already have national stock numbers as a separate AI.

We also suggest that, if you do this, that you grandfather the NDCs that are already there and UPCs because they are already there. Why change them? Why have someone relabel an NDC. But, going forward with your regulation, we suggest you just go to a G-10.

Also, as we always say, you should engage the GS1 global-user groups. I am a staffer from G1. I can tell you what the standard is. I can tell you how it works today. I don't make it up. The users get together and decide how the standard works.

There are several groups right now. One is the healthcare users group. It is a global user

group because we are having these issues in other companies globally in healthcare because the healthcare issues have been raised again and again.

If you go to G-10, I think it will continue to allow your FDA goal for unique identification of all products to meet it. We have very strict rules. We are a rule-based organization. Each packaging size has to have a different G-10, just like a different NDC. We have worldwide compliance with our GS1 standards. Also, we think if you go with the G-10, rather than marking an NDC in the product, you stop other national ministries of health looking for their own national requirement.

Within the last year, we have had three governments come in looking for their own NDC, if you will, on their own products within their own country. This causes problems for the manufacturers because they have to ship an NDC into the U.S. But, for Italy, they have to ship something else, for Germany something else. There are examples. That is not happening right now.

One example is the Italian example. If you are a manufacturer, you ship any drugs into Italy, you must use a serial number. You have to get a serial number and barcode from the Italian Ministry of Printing from Italy. If every country did like this, this would really disrupt the smooth flow of healthcare products throughout.

It also could create possible errors. How could it? If you have two barcodes. If you had a commercial barcode on the product, a UPC so it could be scanned and moved forward and you had another barcode with the NDC. We have seen this in other countries. The nurse is confused, which one do I scan. It causes problems in the database. Also, what do you load in the database? Do you load the G-10 or the NDC?

I went very quickly. That is our overview. For GS1 US, we are a standards organization, global. We are in 155 countries. There is roughly a million members, 280,000 within the United States. 18,000 say that they are in healthcare. A lot of our marketing material says

we scan 5 million times a day.

If you do the math on that, that is roughly 200,000 scans of a barcode an hour, 3,000 a second. A lot of information being processed very quickly throughout the entire system. We are a voluntary in the United States, not-for-profit, not government but member driven. Understand what drives the entire system is members look at it and decide what is the best as we move forward.

It has been said in some of the earlier presenters that the barcode is only one part of the picture. The barcode is scanned. It goes into a database. That is something that the FDA must remember when they go forward with this. The barcode goes into database. It is a pointer to the database. The barcode has no information to it. The NDC is the only variation within our system where it actually has logic written into it for the NDC.

Most of barcodes are dumb numbers. Everyone likes dumb numbers because they just point to the database. We encourage the FDA to adopt

this.

Why would a move from 10-digits to 11-digits concern us? Our system is very structured. A UPC is 12 digits. It has been 12 digits since the 1970s. All the databases are built on this. The scanners are built on this. In the 155 countries where we are giving numbers out to companies, everything is built on this so we don't have a collision.

In summary, real quick--I haven't used my entire time but I did use ten minutes--we suggest that you decouple the NDC number from the barcode.

If you want the item barcoded in there, you could use secondary information or require a G-10 in there. We think that dumb numbers are the best.

Adopt at GS1 commercial global standard. That way products can be shipped throughout the world without these variations in country rules. We think this will avoid potential errors, avoid the charges of a U.S.-centric system and will be able to influence the global standards as we move forward.

Again, GS1 US appreciates the opportunity to speak at this forum. Thank you.

MR. BERNSTEIN: Thank you. Any questions from the panel by way of follow up?

MR. LEVIN: I have a question. Who assigns the G-10 number?

MR. ROBERTS: The question is who assigns the G-10 global-trade item number. A company comes in, pays a fee and they are assigned a labeler code. Similar to your NDC labeler code, we assign a company prefix code, variable length.

MR. LEVIN: So it is assigned similar to what the NDC has done now.

MR. ROBERTS: Correct.

MR. LEVIN: Can the NDC be used in the G-10?

MR. ROBERTS: Yes; it can, in its current configuration.

DR. GARDNER: Can you explain that a little bit as to how that--the UPC is 12 digit. The first digit is product category and the last digit is a check-code. So you have 10 digits in

between that we use the current NDC number; is that correct?

MR. ROBERTS: That is correct. I haven't been in GS1 from the start, but in the 70's, according to the books, the FDA and UCC, at the time--actually Uniform Grocery at the time--got together and determined how to put this together. The UPC's 12 digits for NDCs and the NHRIC's number, when you came in with a labeler code, we put a 3 in front of it so when you pick up an aspirin or something like that, the 3--in our system, the next 10 digits is either an NDC or an NHRIC number.

We don't look at how it is configured. We just give the labeler code. We also go back and check with the FDA to make sure that that company does have that code. We want that piece of paper from you assigning them or, from the NHRIC, we want a piece of paper because a lot of companies come in, they like that NDC for all the reasons that you folks talked about for payment. It is keyed on something that wasn't part of our standard

originally.

DR. GARDNER: If we had to standardize on 10 digits--maybe others could comment on if we had to standardize on 10 digits--would it simplify things if we went to a common standard of 5,4,1, for example? Does it matter for your--

MR. ROBERTS: It doesn't matter.

DR. GARDNER: For other people, it might matter a lot. The conversion from 10 digits to 11 digits is somewhat complicated because of all the different standards and confusion. So all the billing systems, not the UPC billing systems but the drug and Medicare-Medicaid reimbursement billing systems, are, I guess, filled by the NCPDP standards convert to 11 digits.

If we set up a standard way to convert from 10 to 11, would that--like I said, 5,4,1--would that solve your problem?

MR. ROBERTS: I think the question is if you had a standard conversion. As long as you retain 10 digits, and digits not alphas, then we wouldn't have any problem with a barcode system

globally. When you go to 11 digits, when we have huge difficulties.

How do we assign numbers? How does it fit into a 12 digit? You just can't do it.

DR. GARDNER: I guess that is the other issue. Is it necessary to have the NDC in the UPC or is there another way to do that?

MR. ROBERTS: As I said, before the Barcode Rule of 2004, a lot of the over-the-counter drugs just had a UPC in it using the company prefix that they were assigned in the UPC. With the 2004 barcode, they switched and put their NDC in there.

Has there been any change to the marking system? No; the barcode is still scanned. The G-10, that is what we call that number in there in the UPC, is scanned, points to a database and moves on. We don't see any difference why does the NDC have to be. We applauded the idea at time. We thought it was a good idea just to move healthcare forward because we have been trying to get everything marked for years.

But now, as we are moving forward, we are

seeing other global issues with it.

DR. GARDNER: Can you talk a little bit more about the impact of having two barcodes, then, one for the NDC and another as a UPC?

MR. ROBERTS: The impact would be--and then you really need nurses and pharmacists in here. This is all anecdotal evidence that I have heard, a lot from the V.A. They send us all their packages where some of our manufacturers go against the standard or they can't read the barcode. There are a lot of instances where they have had two barcodes on the package. The nurse is confused. Which one does he or she scan?

If they both look like UPCs, they scan them twice or they scan the wrong one first. A lot of times, there are label numbers or they scan the lot-expiration date before the primary information G-10. It fouls up the system and creates errors.

Also, say, for instance, there was a commercial G-10 in there in the UPC and the NDC. If the nurse scanned the commercial G-10 and it wasn't in the database, you would get a "not find."

If you scanned the NDC and that wasn't in there, then you would get a "not find." So they have to scan both. So it could be that they scanned both and then you had a double reduction from the inventories which has occurred in the past. It creates duplication and error.

I see I have lost most of you. Sorry about that.

MR. LEVIN: Another question. The G-10 is specific to the package?

MR. ROBERTS: Yes; the global-trade item number changes as the package size changes. If you will, the UPC on that bottle is different from this bottle. It should be different than a package of six or a case of 12. For inventory purposes, you have to know what you are buying.

MR. LEVIN: Some people use sort of 9 digits to look at just the product and disengage the packaging. Do have anything equivalent for that?

MR. ROBERTS: No; I don't.

MR. BERNSTEIN: Thank you. Next up is

Diane Servello from Watson Labs.

MS. SERVELLO: Good morning. I am Diane Servello with Watson Laboratories. I am the Director of Generic Regulatory Affairs. My department is responsible, among other things, for drug listing, assignment of NDC numbers for the company as well as preparing SPL labeling.

I want to thank the agency for giving me the opportunity to present Watson's concerns with the proposed regulations. In the August press release, the agency stated that having drug makers submit drug information electronically will help keep an accurate, up-to-date inventory of drugs on the market and will maintain more accurate information to make it easier to respond to drug emergencies such as recalls and drug shortages.

Watson fully supports the submission of drug-listing information electronically. We agree that submitting drug-listing information electronically is an improvement over the current paper system and will help to improve the accuracy of drug-listing information.

However, we disagree with the proposal that FDA assign NDC numbers. There are a multitude of reasons why firms should be permitted to continue to assign their own NDC numbers. I will provide five examples today.

Number one. Watson is a drug manufacturer as well as a private-label distributor. We manufacture many of our own products but also use contract manufacturers to produce some products sold under the Watson label. Watson owns the NDA or ANDA for some of these contract-manufactured products. In this role, we are responsible for many of the activities that the proposed rule does not contemplate such as determining the trade dress for the product in the R&D stage.

At the R&D, table or capsule imprint markings are assigned, which are based on the product-code portion of the NDC number. At this early stage in the product development, the determination of the ultimate manufacturing site for the commercial product may not yet be made. Yet, we still need the product-code number to

finalize the trade dress. For this reason, the proposal that NDC numbers be assigned to manufacturers instead of private-label distributors is problematic.

Number two; because NDC numbers need to be assigned very early in the R&D process, Watson has already assigned numerous NDC numbers for products in our R&D pipeline that are not yet drug listed. We have already ordered tablet tooling utilizing these product-code numbers. How is FDA going to avoid reassigning these numbers to other products if they assume responsibility for assigning numbers.

Due to the size of Watson's product line, we currently market products under different labeler codes. This is done to separate our various business units. The proposal to use only one labeler code for any new NDC numbers assigned by the FDA would disrupt our business process.

Number four; currently, Watson does not use different package codes for each level of packaging. To change this practice would cause a

major disruption in our business processes by causing us to reconfigure the business software we currently use to control our manufacturing, packaging and distribution processes.

Number five; NDC numbers are used as identifying codes for a myriad of other activities including interactions with other governmental agencies such as the DEA for Arcos reporting and various agencies for Medicaid-Medicare reimbursement.

In addition, many firms use 10-digit NDC numbers to track their own internal business processes and/or documentation such as manufacturing records, analytical test methods, validation reports, et cetera. Any changes to the current system will cause major disruption to these processes.

As stated previously, Watson fully supports the electronic submission of drug-listing information. We believe this is significant improvement over the current system and will improve the accuracy of the data contained in the

system. However, the proposal for FDA to assign NDC numbers will cause major disruptions in our business processes.

We advocate allowing firms to continue to assign their own numbers according the current practices. We believe the agency could devise an electronic system that allows firms to enter their own information while still accomplishing the goals of the proposed rule.

Thank you for the opportunity to present my concerns.

MR. BERNSTEIN: Any follow up for Diane?

MR. LEVIN: Yes. I have a few questions.

How early in the process do you assign the NDC, how much time before you go to market, would you say?

MS. SERVELLO: I would say it is sometimes three or four years before.

MR. LEVIN: So if the assignment is made three or four years before, that would accomplish what you need. Would that accomplish what you need?

MS. SERVELLO: I think that one of our concerns, and I didn't mention it, is the time factor, too, because if it is a process where we have to apply for it and then wait 60 days for it, I don't think that is going to allow us the flexibility we need and what we have under the current system.

MR. BERNSTEIN: What time factor would be acceptable?

MS. SERVELLO: I would like at least five working days. I get 20 minutes to do it right now.

MR. LEVIN: you said there was a problem with assigning the numbers, duplicate numbers, or whatever. How do you avoid assigning those?

MS. SERVELLO: I assign numbers currently through an access database where I have all the possible numbers that are available. If that spot is blank, then I have that number available.

MR. LEVIN: When you were talking about the different business units, can you elaborate on what those business units are for the different labeler codes?

MS. SERVELLO: Watson currently has a branded division and a generic division. For our generic division, we use a 4,4,2 configuration. For our branded division, we use a 5,3,3 configuration. We also just did an acquisition. That division is going to maintain their labeler code so that is another division that requires another labeler code.

MR. LEVIN: So, through an acquisition, you are going to keep them as a separate entity at least inside of your company.

MS. SERVELLO: Yes.

MR. LEVIN: You talked about the level of packaging. What level of packaging do you assign the NDC?

MS. SERVELLO: We assign the NDC number for bottled products. But it is the case quantities that we don't assign a level at this point,

MR. LEVIN: So you assign it for the bottle but not at the--you have a case of 12 bottles. not at that level.

MS. SERVELLO: Yes. Even for injectable products, we would assign it for the carton that contains the vials but not the outer shipping case.

MR. LEVIN: Okay.

DR. GARDNER: Can I follow up on a few more of these? As we are currently contemplating, we would have the company submit the NDC number they want and then we would not accept that only if it didn't meet formatting requirements or was duplicative of another product.

It is possible, because of the 5,4 labeler code configuration that, when you collapse 11 digits to 10, you get a duplicate. You would never know that within your company. But, within your company, with your labeler code, you would have total control over your own product codes and package codes, again, as long as they meet the requirements. The requirements will change.

If you change the inactive ingredient, for example, or a significant inactive ingredient, then it would get a new number, it would have to get a new number. Would that disrupt your business

processes?

MS. SERVELLO: I don't think so. As long as we could submit the requirements, you would accept that number.

DR. GARDNER: There is no reason we wouldn't accept it I can think of other than, as I mentioned, the formating stuff. But, anyway, that type of interaction--what I am getting at is if we continue to give the companies control over the numbers they request, would that resolve most of the issues you have brought up?

MS. SERVELLO: Yes.

DR. GARDNER: Okay.

MR. LEVIN: I have another question. Coming back to your business units, how do they function as far as operation in your company? Are they separate? Do they have separate chains of command, contact people.

MS. SERVELLO: They are all subsidiaries of Watson Pharmaceuticals, but they do operate--the branded side and the generic side operate as different divisions of the company.

MR. BERNSTEIN: Thank you very much. I guess we seem to be keeping the trains running on time this morning. We have a break scheduled until 10:45 and then we will pick up again with additional speakers.

[Break.]

MR. BERNSTEIN: We will move right back into the speakers. The next speaker is Dr. Thomas F. Willer who is with Hospira.

DR. WILLER: My name is Tom Willer. I am the Director of Regulatory Affairs at Hospira. I would like to focus my comments on legacy, NDC numbers and compliance.

As noted here, the National Drug Code numbers are one of the linchpins of the healthcare system. NDC numbers are used throughout the drug-supply chain and users extend from pharmaceutical companies, distribution system, medical community, insurance industry as well as the government, itself.

Currently, NDA and ANDA holders assign NDC numbers for the product code of their own products.

This has been the case for decades and is deeply embedded in the internal processes of sponsors specifically and the healthcare system in general.

The NDC number is not only used for marketing purposes. It also plays a pivotal role for sponsors and the R&D process where the number is crucial for internally tracking compounds in a company's pipeline. As noted by one of the earlier speakers, the R&D process begins years before a product is launched. Therefore, under the current recommendation by the agency, the NDC number would have to be applied for and granted years before a product launch or before an ANDA or NDA approval.

The NDC number is also used in identifying the export of scheduled drug compounds for DEA.

Now as noted by earlier speakers, the August, 2006 proposed rule contains the key NDC-related points noted in this slide, namely universal standard format, drug-industry requests new NDC numbers. FDA signs them. Current NDC numbers remain unchanged provided these numbers comply with the new rule when finalized. Lastly,

non-compliant NDC numbers would be reassigned by the agency.

NDC numbers have been used for decades. The FDA has accepted these numbers via its drug-listing function. The FDA has not routinely contacted companies requesting changes to currently used NDC numbers. Existing NDC numbers are already accepted, a critical part of the supply chain, and being interwoven with both public and private healthcare organizations.

The proposed rule intimates that some unknown number of NDC codes may not be correct. This raises some questions. For example, how many NDC numbers currently exist? How many does the FDA estimate may not meet the 21 CFR 207.35? In other words, how big is the problem, or potential problem?

Again, we are talking about thousands of drug products and legacy NDC numbers. Creating NDC numbers for various levels of packaging, as noted, for the container, carton, as well as the shipper or corregate increases the universe of NDC numbers,

increases FDA cost to assign new numbers, increases FDA cost to record and monitor new numbers and seemingly has no additional benefit to patient safety.

So it is not clear how the shipper NDC number has any effect on the actual patient.

Current distribution systems are already based on existing NDC numbers. An NDC number changeover could cause drug shortages as companies navigate expiration of products with legacy NDC numbers and introduction of products with revised or new NDC numbers.

Tens of millions of dollars to the pharmaceutical industry would be a cost as well as healthcare enterprises is an understatement. This is especially distressing in light of the increased cost of healthcare and financially strapped hospitals and medical service providers. In this end, the burden ultimately will be born by patients.

First and foremost, industry needs to know what criteria will the FDA use to judge legacy NDC

numbers for compliance. From a legacy standpoint, there are thousands of products which fit the compliance criteria over the decades. For instance, the FDA approved Hospira's first NDA in 1946. The FDA has not notified the company of any compliance issues with any NDC number in the past 60 years.

Massive changes to the NDC system would require a much longer implementation period than the proposed three years and nine-month time frame.

Two issues to consider, if there is a compliance issue to reassign NDC numbers from numbers currently meeting the needs of the marketplace. For example, many infusion devices already read barcodes or NDC numbers would have to be recoded one by one. An infusion device is a pump at the hospital level.

Also reprogramming and changes to databases by all parties is seemingly not a productive use of limited funds and may disrupt reimbursement as well. A change to the existing NDC rule would cause a heavy burden on the

pharmaceutical and medical providers. The internal processes and systems would have to be reevaluated and changed.

All parties in the supply chain incur costs from manufacturers, warehouses, distribution centers, medical offices, hospitals to insurance and other reimbursement parties. A unique package-code system encompassing every company seems daunting since there are only two digits available for the multitude of packaging configurations.

If current legacy NDC numbers that meet market needs are retained, progress to the proposed new FDA allocation of NDC numbers can easily proceed. We also strongly urge the FDA to put in place a robust security system to protect sponsor confidentiality when requests are made for a new NDC number. As noted earlier, this occurs early in the R&D phase of a company and we need that number and not let anyone know that it has been allocated.

As I have discussed, this isn't simply a matter of an NDC number. This is an issue that

could include barcoding and reprogramming. Consideration of expanding currently used barcodes would not produce the dislocation issues of requiring new changes to NDC numbers with the current market products.

Company mergers and acquisitions; how will the agency handle these frequent occurrences and the NDC implementation time? System learning curves which involved initial glitches and breakdowns occur. Reprogramming NDC numbers in all computer databases throughout the supply chain inevitably would be slow.

Pipeline confidentiality, as I have mentioned, and delay of new product launch and marketing, allocation of the NDC number must be confidential and must be allocated in a timely fashion. As noted earlier, a five-day period or a 30-day period would probably meet our needs.

A finite pool of numbers for an infinite amount of number configurations, we see the number of NDC numbers as limited and not the 100,000 number or pool that the FDA projects.

In summary, we urge the agency to consider retention of all current legacy NDC numbers in the marketplace.

MR. BERNSTEIN: Thank you. Any questions for Dr. Willer?

MR. LEVIN: Moving forward, then, for new products, following a set up rules, do you have issues with that?

DR. WILLER: We support the idea. Our only worry is how can the FDA do it? Right now, we have a 4,4,2 code. So the first four of the label code, they are gone. The next four are the drug code. There are only 9,999 numbers. So Hospira already has allocated about 3500 of those numbers.

So when the agency gets ready to allocate our next NDC number, they have to know what has already been used up, at least in those four digits for us.

I don't know how you will do that. Now, maybe as the NDC numbers become more mechanized under Dr. Gardner's system for drug listing, maybe that will be easy to manipulate and to understand.

If that is, then that is good.

DR. GARDNER: So you don't think 100,000 unique numbers for Hospira is enough?

DR. WILLER: I don't know where the number 100,000 comes from? There is 4,4,2. You only have four numbers.

DR. GARDNER: That is 10,000.

DR. WILLER: Yes. That is not enough over the long term.

DR. GARDNER: That is because you use two for a package code.

DR. WILLER: As mentioned earlier, the agency wants a number for products going outside the United States. We assign under that packaging code a unique country destination. So we have a specific number for Ireland or for Germany or for ex-U.S.

DR. GARDNER: So if you ran out of product-code numbers, then a new labeler code, would that solve your problem?

DR. WILLER: Correct.

MR. LEVIN: I have a question about what you just said about that you used different codes

for different countries.

DR. WILLER: Correct.

MR. LEVIN: Can you tell me more about that?

DR. WILLER: We manufacture some products for export here in the United States. In order to keep it clearer at the manufacturing site, we want to assign--we have assigned a unique NDC number to follow that product during the manufacturing stage so that if the product formula for Italy was different than the one for the United States, we would make sure that that number is associated with that product. So it is a security issue.

DR. GARDNER: The product formulation or packaging?

DR. WILLER: The product formulation. It could be packaging but it more likely is formulation.

DR. GARDNER: But if it is formulation, it would have to have a different product code.

DR. WILLER: Under the proposal; yes.

DR. GARDNER: That is current.

DR. WILLER: Yes.

MR. LEVIN: But some of these products are the exact same formulation? You are just sending them to different locations?

DR. WILLER: Correct.

MR. LEVIN: Then you assign another product code for your own internal purposes. These are never made public, these numbers. They are never used. Am I misunderstanding that?

DR. WILLER: I am not an expert on exporting of drugs so I don't know for sure.

MR. LEVIN: Okay.

MR. BERNSTEIN: Thank you. Next up is Scott Melville from the Healthcare Distribution Management Association. Following Mr. Melville's remarks, we should have some time for some discussion if there are any audience questions. If you don't want to use the microphone, you can also write them down and send them up here.

MR. MELVILLE: Thank you and good morning. I am Scott Meville. I am Senior Vice President of Government Affairs for the Healthcare Distribution

Management Association. I commend the FDA for holding this important public hearing this morning.

I thank you for the opportunity to comment on behalf of HDMA and our members.

HDMA represents the nation's primary full-service healthcare distributors. Our 40 members include large national companies and small regional family-owned businesses. Each day, our members deliver 9 million healthcare products to more than 144,000 pharmacy sites across the country in all 50 states and U.S. territories so there is a lot of volume going through our members on any given night.

HDMA supports the FDA efforts to clarify the regulations on drug establishment, registration and listing in much of the proposed rule. However, there are two critical parts of the proposed rule that will have an enormous and very negative impact on our members in the pharmaceutical-supply chain.

Those two areas are the definition of relabeling and the assignment of NDCs on new packaged drug products.

With regard to relabeling, the FDA's proposed definition of relabeling in Section 207.1 is defined very broadly to meet any change or addition to the label or labels on a drug or drug package. HDMA has grave concerns regarding the breadth of this definition.

HDMA distributors, as I said, ship millions of prescription drug units each night to customers across the country. To do so efficiently, it is common practice for our members to affix stickers, barcodes, tags or other identifiers to drug packages to track inventory location, identify product origins and/or ensure proper returns from pharmacies.

For example, stickers may confirm or convey important handling information for customers such as "refrigerate upon arrival" or direct a delivery of drugs to a particular part of the hospital or medical facility. Some distributors manage inventory by applying proprietary serialized codes to drug packages that enter their facilities. These additions allow a company to identify and

trace the drugs entering and leaving the distribution center.

Some distributors also apply codes to drug products in order to efficiently and effectively comply with the FDA's barcode rule. Requirements under the PDMA final rule and/or state drug pedigree laws; to improve compliance with the State of Florida's recent pedigree law, for example, some HDMA members add serialized barcodes to the drug-product container.

Currently, also, some distributors participate in radiofrequency identification pilots to study the use of RFID tags in the prescription-drug supply chain on appropriate products. As RFID programs further develop, distributors will need the flexibility to sticker or tag products without also triggering the listing or registration requirements of this rule.

I have an example of a very simple tag that many of our members use, but this is an example of a type of a tag a distributor might put on the bottom or side of the bottle when he sends

it out to his customers. It explains where the product should be returned to or reordered from.

I also have a photo here of a license plate, essentially, a code that a distributor may affix to the bottom of a product. This is an example of what one distributor is doing to comply with the state pedigree requirement to be able to track a unit of that product since, as of now, most products coming from manufacturers are not serialized. They simply have a lot number and an NDC number. Many, many pedigree laws require them to get down to the unit level. So there is some additional marking that is necessary to comply with those laws.

These examples of distributor-applied stickers and tags do not otherwise alter the drug's original label, labeling, package or outer container. They do not affect the safety, purity of potency of the drug and do not disturb its existing packing configuration in any way.

Thus, if the definition of relabeled remains as proposed, many common security and

inventory tracking best practices conducted today by distributors would, we believe, unintentionally trigger the relabeling designation and requirements of this rule. If left unchanged, FDA would have to assign tens of thousands of new NDC numbers to ensure compliance.

Given that the agency stated in the rule's preamble that most drugs would be able to retain their current NDC number, we believe FDA did not intend these consequences. In our written comments, we will propose an alternative definition of relabel that we believe both accomplishes FDA's goals and permits continuation of common distributor stickering, tagging and barcoding practices.

The second issue with which HDMA would like to discuss today is repackaging. We believe this is a practice that would be significantly affected by the proposed rule.

HDMA members perform many forms of packaging. For example, a packaging company may simplify the last step in the manufacturing process

such as contract processing or aid in the dispensing of products to the patient for use for unit-dose systems such as unit-dose packaging in hospitals. However, today I will limit my comments to the proposed rule's effect on another type of packaging known as retail-service repackaging, a practice that was earlier discussed by the National Association of Drug Stores representative John Coster.

A retail-service repackaging company purchases finished solid oral dosage-form drug products from the manufacturer and repackages them into smaller quantities. The smaller packages are sold and delivered to retail pharmacy customers bearing the manufacturer's applicable NDC number for that package size.

Retail-service repackaging safely and effectively offer package sizes that increases inventory efficiencies, eliminates waste and provides enormous value to our members' retail pharmacy customers.

HDMA members who conduct retail-service

repackaging do so in a safe, secure environment. All repackaging companies must register with the FDA as a manufacturer and operator in strict adherence with current good manufacturing practices. In addition, repackaging companies must be licensed as distributors under applicable state laws.

Further, our repackaging members include their name, address and repackage lot number on each and every repackaged drug product enabling the product to be tracked back to the repackager and ultimately the original manufacturer.

Above and beyond these regulatory requirements, HDMA has established recommended guidelines for pharmaceutical distribution-system integrity and recommended guidelines for pharmaceutical repackaging integrity. HDMA's repackaging members also voluntarily and independently follow even more aggressive security policies including those that require that they purchase the drug products directly from the manufacturer of the product, itself, the original

manufacturer.

The proposed rule would disrupt the safe, efficient and cost-effective business service by requiring a new repackager NDC on the product. Under CMS requirements, responsibility for payment of the Medicaid rebate follows the NDC number on the drug package. If the manufacturer's NDC number appears on the package, it is responsible for the rebate payment.

If the repackager's NDC number appears on the package, the repackager is responsible for the rebate. By requiring that retail repackaged drugs bear the repackager's NDC number, the rule effectively shifts the burden for Medicaid rebate payments from the manufacturer of the product to the repackager.

To better understand the business implications of this shift, NDC retained the Moran Company, an independent consultant firm. Their analysis concluded that repackaging companies will not be able to absorb the rebate cost given the industry's traditional slim profit margin. If the

proposed rule becomes final and repackaged drugs must bear the repackager's NDC number, the consultant confirmed that distributors will no longer be able to offer this valuable service to pharmacy customers and will exit the retail-service repackaging industry.

Considering the economic impact and safety and security controls already in place, requiring a new repackager NDC number, we believe, is not warranted nor will it provide additional levels of security. However, if FDA is convinced that an additional identifier is needed, we believe the alternatives that HDMA and NACDS have previously described to the FDA are still valid and will satisfy the rule's intent while allowing the repackaging industry to continue to serve its pharmacy customers.

Given the significant impact of the proposed rule, we ask that the agency reconsider those alternatives. Either one would formalize the application of the unique repackaged item code and would meet the FDA's objective of further

identifying the repackager and repackaged product without requiring a new NDC.

We hope FDA will seriously consider the implications and alternatives presented by NACDS and permit a path forward that enables our pharmacy customers to continue to benefit from repackaged products. If, however, FDA proceeds with implementation of the rule, NDC may ask, on behalf of its members, that the agency allow sufficient time to orderly structure the retail-service repackaging operations.

For prescription drugs, FDA had proposed a three to five-year implementation period. HDMA members estimate the pharmaceutical supply chain will be five years to adapt to this new rule. Repackaging companies will need to renegotiate their contracts with both customers and suppliers, change and phase out retail-service repackaging operations and terminate or reassign work force.

Our members pharmacy and hospital customers will need time to evaluate their supply options and locate alternative sources for the

product they obtain from retail-service repackagers. Finally, manufacturers, some of which rely on repackaging to meet pharmacy needs, will require time to alter their operations and possibly increase their own packaging capacity to produce additional smaller units for distribution to retail pharmacies.

To conclude, HDMA appreciates the opportunity to share views with the FDA. We commend the agency for proposing a rule intended to improve the quality and timeliness of information available to patients and healthcare professionals but we believe the proposed definition of relabel would undermine those stated goals by adding a more complex numbering and relabeling process into the current distribution system.

We ask that the agency carefully examine the proposed definition of relabel and narrow it to permit barcoding, tagging and other stickering practices distributors use to ensure a safe and secure delivery of products to their pharmacy and other healthcare-provider customers.

Second, we ask the agency reconsider its proposal to require that repackagers use their own NDC number and, instead, allow the continued use of the manufacturer's NDC. If the agency chooses not to amend the proposal as we recommend, we urge full consideration of the implications to the entire pharmaceutical supply chain by allowing the five-year lead time needed for manufacturers, repackagers and the retail industry to make alternative arrangements.

I thank you for the opportunity to provide these comments today.

MR. BERNSTEIN: Thank you. Questions?

DR. GARDNER: The repackaging issue, it sounds to me like this is primarily a rebate issue. This repackaging item code--is there a need to have two separate codes on there, an NDC and a repackaging item code rather than just a different NDC number?

MR. MELVILLE: Certainly, the NDC number is key to determining who pays the rebate.

DR. GARDNER: Aside from that question, is

there any reason to have two different identifications numbers?

DR. WILLER: No; absolutely not.

DR. GARDNER: So it is really a rebate issue.

DR. WILLER: Yes.

DR. GARDNER: And that is, to me, a separate issue. That is a Center for Medicare-Medicaid Services issue as to how they manage their rebate program rather than a unique product-identifier issue.

DR. WILLER: Let me alter that answer a little bit in that, if it is truly the intent of this rule to identify the origin of the product, then the NDC number on the bottle with the repackager's current identifier, the practice of placing the repackager's name on the label, that is the addition that a repackager product adds. It is required to add "repackaged by" on that label.

So you have the NDC number, the manufacturer of the product. Then you have, in human-readable form, the repackager's name. You

are able to identify who repackaged that product and that repackager is able to identify, obviously, the source of the product, the source being the NDC number that is on that bottle.

DR. GARDNER: But the new NDC number for the repackager would serve the same purpose as having that RIC? number.

AUDIENCE: [Chorus of no's.]

DR. WILLER: I hear the people in the audience do not agree with that.

DR. GARDNER: I am asking.

DR. WILLER: Perhaps that could be during the question-and-answer session. It would not serve the same purpose because, under the current Medicaid rebate rules, the manufacturer--

DR. GARDNER: There are two separate issues here. One is the unique identification of the product. We go by NDC. Does that RIC serve another purpose that would not be met by having a new NDC number is my point, other than the rebate issue.

DR. WILLER: Oh. Sure. I think the

agency is required to consider the economic implications of every rule that it undertakes. By going and putting the repackager's NDC number on, you would essentially put that industry out of business. So, by keeping the old one on with a RIC, the industry could continue to provide the benefit to its customers and, at the same time, provide that additional level of identification that it appears the FDA may desire to have.

DR. GARDNER: I am not saying that we would tend to interfere with the rebate process. That is certainly not what we are doing. What I am saying is there are two issues here. One is the unique identification of a product which, in our current thinking, that should be by NDC number. But a second is the rebate issue which is an issue with CMS, not with us. But we certainly would get it worked out before we went forward.

DR. WILLER: We recognize that the NDC number that goes on the repackaged product to the customer is the NDC number for that exact product that that patient or that customer is receiving.

It is the manufacturer's product, so everything that is in that NDC label that describes that product that is in that bottle.

They are repackaging the manufacturer's branded product and putting it in a bottle.

DR. GARDNER: I understand that but the repackager is, by definition, a manufacturer. They've changed the product. So that manufacturer needs to be identified in our listing system as having touched or dealt with, manufactured that product. That wouldn't happen under--by using a RIC, because we don't use the RIC in our listing. We use the NDC. So that is what I am trying to get clarification on.

DR. WILLER: Our members do have to file listing for an NDC number. The Chairman of our Packaging Committee, Tim Booth, is her. Tim, do you want to talk about your company's practice as far as the listing?

MR. BOOTH: My name is Tim Booth. I am the Chair of the HDMA Packaging Committee which we have several members, three larger members being

the wholesale distribution community.

In the filing process, we do have to file with the FDA for drugs and list drugs that we do repackage. On the label for the branded repackaging that we are referring to is the NDC of the original manufacturer. We do, however, list with the FDA with our own NDC number for that repackaged drug in the listing process. Therefore, we have complete traceability from the original drug, the original manufacturer, to the repackaged product, very clear traceability, both through the listing process and also in our systems that we use to track the drug from the purchasing to the actual sales side of the business, complete traceability.

Does that answer your question?

MR. LEVIN: Again, it seems like it is this rebates issue, which number is on there. That is the main issue.

MR. BOOTH: That becomes a thrust of what is--by changing NDC number, that becomes the thrust of the issue for our business; correct. But, from a traceability and product standpoint, we have

complete traceability from the original manufacturer, and we do buy from the original manufacturer directly, to the actual repackaging process to the sale of the drug through to the retail pharmacy, complete traceability in both batch records of production, purchasing activity and the listing process.

MR. LEVIN: The repackager item code, can you give me more about that? I am sorry, but I don't know--

MR. BOOTH: The repackager item code that we are referring to is a unique identifying number that we will assign to that specific product. It is an internal number that we generate in our business practice that we can identify that unique number. So it is unique to every single item with, in this case, the McKesson distribution-supply chain.

MR. LEVIN: It is unique in your own system.

MR. BOOTH: It is unique to our system; correct.

DR. GARDNER: So there would be a one-to-one match between the RIC and the repacker's NDC.

MR. BOOTH: Yes. Absolutely. There is a unique connection between the internal economic number, as we call it, the identifying number, the repacker's NDC that we file and also the manufacturer's NDC number that is placed on the label, a very acute connection there.

MR. LEVIN: So when you go through the listing process, you can identify the NDC of the manufacturer that this is in your repackaging.

MR. BOOTH: On the listing process, we put on the actual filing the NDC that we are filing for our product. We also refer to the original manufacturer on this listing process and the labeler code of that original manufacturer. So there is, again, a unique connection between our systems.

We also use those systems to actually create the pedigree for a product that we are shipping out to Florida and to other states that

require a pedigree.

Any other questions on that? Did we answer the question sufficiently for you?

DR. GARDNER: Yes. Thank you. Is this the last presentation of the morning? Let's just move to the open discussion.

DR. WILLER: Thank you very much.

Open Discussion

MR. BERNSTEIN: Did anybody have any questions or comments from the audience?

MS. BENYO: My name is Laurel Benyo from Ben Venue Laboratories. We are both a generic drug-product manufacturer as well as a contract manufacturer for branded drug products. I have three comments that developed as I have been listening to the other speakers. Thank you for this opportunity.

Number one, with regards to timing, you have been told over and over again, we are the same. Our R&D uses NDC number. We assign numbers approximately four years prior to the time that they actually reach the market, ideally, if

everything goes well.

But there is also another timing issue that we have. We do private label. We have received contracts from GPOs where we are expected to launch in, like, a week. I assigned an NDC number in 20 minutes, as somebody else spoke. So we would need very, very quick turnaround on NDC numbers, the approval, because we are expected to do product launches in a very timely manner when we do get contracts like this or private labels.

We do turn them around very quickly. 30 days would not satisfy some of our private-label distributors that we try to launch immediately.

The next comment is regarding 10 digits. We are a small buy-in parenteral. The majority, about 70 percent of my drug-product labels are 2 cc vial labels. I have a great deal of difficulty currently with the RRS barcoding that will be used.

We try to always use the 7 ml barcode. We have gone down the a 5. This does cause difficulty. We want to make sure that our barcodes are always legible and easily scanned by the end user.

Adding additional digits would be very difficult. Our unit cartons do use the UPC. I thank John Roberts for pointing out that it is a 12-digit number and that it would cause a great deal of concern if it was to go to 11 digits. We would no longer be able to use the UPC on our cartons.

Our final thing; we have a 5-digit labeler code so we have 5,3,2 configuration. Our generic drug business has only been around for 14 years. We have always used one-third of the available digits in that middle three. We have used over 300 numbers. If you look at that, in 14 years, we do have a finite number available to us.

I know the gentleman was talking about having 9,999. But we only have 999 in that middle digit. We have already used a third in 14 years. So we do see a finite possibility in how we manage our NDC numbers. So I respectfully request that we continue to allow industry and ourselves to assign these numbers based on the need for timeliness, the need for control. It is a great deal of numbers.

You look at all of industry and it would use a great deal of the FDA's resources.

So thank you for this opportunity.

MR. BERNSTEIN: Thank you.

DR. GARDNER: Again, if you ran out of product-code numbers and we were able to issue you a new labeler code, would that solve your problem?

MS. BENYO: It would from that point forward. But then you have to relate them together. So we would have part of our product line using our 5,5,3,9,0 labeler code. Then you are going to switch in the middle of our history to a new labeler code. Whereas, if we are able to continue to control them, then we can use--and we do assign new NDC number to different formulations as they come through.

I admire your use and restrictions that was put up by you at the beginning. Those are things that we comply to now. If the proposed rule continued to make industry comply with those use and regulations, we do now and we would continue to do so. But, yes; if you assign a new labeler code,

well, then, we would open up with another 999 digits in the middle. But you would be disrupting the history in the middle of our list of numbers.

MR. LEVIN: I have a question. When have you estimated that you would run out of numbers? How many years?

MS. BENYO: Currently, we file 12 ANDA applications every year with the agency. We have, on occasion, had 21 drug launches. We average approximately 10 drug launches a year. So, like I said, in 14 years, we are growing very, very quickly. We started with one or two drug launches a year and now we are going up to 10.

In addition to that, we do private label. We use our labeler code and assign brand-new middle numbers for all of our private labels from GPOs. We have one drug product that we have four private labels in addition to ours with three dosages. So, right there, you have 15 numbers on just one drug product. So, given our past successes and a good hope for the future, and we are already a third of the way in 14 years, then

you can just figure out that, hopefully, if this continues, we are talking 25 years.

MR. LEVIN: So 25 years from now.

MS. BENYO: Yes.

MR. BERNSTEIN: Thank you. Did you have a comment? Go ahead.

MR. WRIGHT: Thank you. Good morning. My name is George Wright. I am Vice President and one of the principals of Product Identification and Processing Systems. My company has a 25-year history of involvement in the barcoding standards, development and implementation arena particularly in healthcare.

For the last 15 years, I have served on the Health Industry Business Communications Council's Automatic Identification Technical Committee. I am a certified solution provider for the GS1 system and, most recently, served as editor of HDMA's new Barcode Implementation Guideline.

I would like to address a couple of comments on the NDC, its length and the capacity of the system. John Roberts did us a great service in

emphasizing that nothing beyond 10 digits in an NDC can be accommodated within the present GS1 system.

It is not a question of you would like to go to 11. You may statutorily, of course, but it would completely undermine the use of the UPC and the barcode rule as promulgated by FDA.

So, from that perspective, and there is a great deal of detail behind that--I don't think everybody wants to have their eyes glazed over here for it. My public comments in writing will cover this, but you cannot go to 11 without completely disrupting the barcode rule as implemented and the UPC system as used today at every level of packaging in the United States.

With respect to the capacity of the NDC system, on Page 85 and elsewhere in your docket document, you talk about a capacity of 100,000 labeler codes. On one page, in particular, on Page 85, you refer to the possible confusion that would emanate from a labeler code of 1,2,3,4,5 followed by a 3,2 configuration with labeler code 1,2,3,4 followed by a 4,2 configuration.

The age may have overlooked the fact the 30 years ago, you specifically reserved code numbers 1000 through 9999 never to be used. They cannot be used or you would have exactly this problem you alluded to. If you go to the firms.text listing as published currently, you will find that 4-digit labeler codes cease at 0999 and only begin again at 10,000.

There are two exceptions in the current listing. I believe them to be erroneously assigned codes, but 30 years ago, the way duplicates were avoided was to set aside those 9,000 numbers from 1000 to 9999 never to assign them.

So there is, in my opinion, no prospect that there can be duplicates within the current NDC system that you have 91,000 labeler codes available for assignment and that that will meet the foreseeable needs of this industry for as long as we are constrained by UPC.

Thank you.

MR. BERNSTEIN: Thank you. Questions?

MS. HORN: Hi. I'm Heidi Horn. I work in

regulatory affairs for the Perrigo Company. I first want to thank you for the opportunity to come today and share ideas and open up a dialogue.

I have a question as it relates to the filing of labeling information--electronic labeling filing as part of the drug-listing process as it relates to monograph products. For ANDA and NDA products, SPL labeling is part of the submission process. But for monograph products, SPL labeling is not a requirement today.

So my question is will other electronic forms of the labeling be accepted as part of the drug listing requirement? Maybe now is not the time to answer it.

DR. GARDNER: I think that would be answered in the final rule, but that is an issue we need to determine for the XML SPL format that is required for prescription application drugs. But then we defined, in the proposed rule, the content of labeling for over-the-counter drugs as the drug-facts label. We would develop a mechanism to do that.

MR. LEVIN: It might help if you put your question in the form of a comment, turn it around. What are the issues that you have.

MR. HORN: The issue would be that, for monograph products, electronic form of labeling does exist. But it doesn't exist in SPL format. Therefore, manufacturers of monograph products, in particular Perrigo, as store-brand manufacturer, we would have to create SPL labeling for all of our products. Annually, we develop 13,000 different labeling components. That is a lot of extra work.

MR. LEVIN: You said the labeling exists now. Can you give us details.

MR. HORN: In electronic format? Yes. Today, the labeling exists in Pediafile format.

MR. LEVIN: That labeling is also, I guess, in a word-processing format, too?

MR. HORN: Yes.

MR. BERNSTEIN: I believe the preamble in the proposed rule contemplates, at this point, use of sufficient PDF information other than the specific exceptions that are named.

MR. LEVIN: Just in the comments; is that right?

MR. BERNSTEIN: That's right. But I think those things are subject to review as the process moves forward. I don't know that anything has been set in stone on that yet but I would point that out. That is where the proposal stands right now.

DR. GARDNER: The rule does state that we will submit a guidance that would specify the format. What that is has not been determined.

MR. HORN: I have another question that I will try to make a statement this time around and that is as it relates to the labeling of monograph products. I believe that it would your intention to post that labeling also to be available to pharmacies and physicians.

I guess my quandary or my concern would be that, with the monograph products--labeling changes with the monograph products are primarily driven by changes in the monograph. If an additional warning was needed on a monograph product, we would not necessarily have to request a new NDC number and

then subsequently file the revised labeling with FDA to then be posted on the site and have you taken that into consideration.

DR. GARDNER: The current mechanism for posting labeling is the XML format. So, if it came in in XML format, we already have the capability to do that, to post those. If it didn't, then we would have to develop a new capability and that would be a different process.

MR. HORN: Okay. So it goes back to software.

DR. GARDNER: You can see the direction we are thinking. Whether we get there or not is not yet decided.

MR. HORN: Thank you very much.

MR. BERNSTEIN: Thank you, Ms. Horn.

MR. LAY: Good morning. My name is John Lay. I am the Director or Regulatory for Apotex. Currently, we have 68 applications pending with the agency. We currently follow about 45 annually.

My question is, with that many applications, we use multiple manufacturing sites.

Therefore, up to three sites, actually, will produce the same drug and this is approved in the applications. What your rule is asking me, or directs me to do, is to produce the same product, same formulations, at three sites and essentially have three NDC numbers out on the market with my name on the product.

I think that is going to--and after talking to the wholesalers, the cardinals of the world, that is going to cause confusion from their system because it is going to overburden their system by having to track three NDC numbers instead of just one.

That is one of the major concerns that Apotex has over this.

MR. LEVIN: Can I just have a clarification. You said your company has three different sites and you would have different NDC for each site?

MR. LAY: Well, currently we would produce it under one NDC number at three different sites. Therefore, the cardinals McKessons would track it

accordingly. By the rule, the way it is proposed, they would then have to track three different numbers and actually have to order the product depending on what number.

DR. GARDNER: That is not my understanding of what we proposed. If it is all within the same company, the site has to be listed but it would not have a separate NDC number. It is only if you are buying from different companies that you would then have to have a different number--

MR. LAY: That is correct. If you use a contract--and that is my point here--if you use a contract manufacturer to produce your product, it will have another labeler code. It will not have your labeler code on it. That is the point here is that the contract manufacturers product, what they produce on your behalf, according to your ANDA that is approved, or NDA, it will come on the market with multiple NDC numbers for the same product.

DR. GARDNER: That is an issue we have to think about how to address because the contract manufacturers, as a whole, are a grey zone. If it

is clearly a different manufacturer you are purchasing from, then I think it is clear. But if it is within the same company, it is also clear. It is when you have a contract manufacturer that it is not so clear.

MR. LAY: But what if the second or third manufacturer is located in a different country; i.e., in India, as an example. That is going to be the same situation as a contract manufacturer.

My next question is--it is a point and then a question--

DR. GARDNER: Back on that, I think that our public-health perspective on this is that we need to know--if we want to trace a drug back to where it was really made, if there is a problem and it has to be recalled, or whatever, we need to be able to identify which product goes back to which manufacturer and that is the thinking behind uniquely identifying those products through the NDC code.

MR. LAY: I would agree with that except I do my recalls based upon my lot numbers, not based

upon an NDC number. It is always lot-number driven. Really from a CMC's perspective, it is always lot-number driven, not NDC driven.

Now, another concern is, and I know there are numerous companies in here that do the same thing as Apotex is I actually manufacture my product according to an NDC number. That is essentially my item number. So my NDC number does, in fact, go to a specified market for a specific bottle size, whatever the case may be.

My concern is I am going to change 2700 batch records to meet the requirement so where my batch records, again, match my NDC numbers, that could drastically change. And the economic impact of that change is enormous. It really is.

MR. LEVIN: So you have multiple contract manufacturers. Your issue is with new NDCs for each one of those.

MR. LAY: The labeler code; yes. And not even multiple contract manufacturers but multiple sites and geographical locations throughout the world that are, in fact, are approved to ship into

the U.S.

The next point I would like to ask, based upon the pedigree rule that is now on a stay in the Eastern Port of New York, has there been any conversation between the FDA and the states to try to alleviate the conflicts of interest between the states or the conflicts between the FDA and the states because the states do have, and the state formularies, do have registration requirements that, if the states are not involved in, we are going to go back into the pedigree requirements right now that the FDA essentially told the states, under the PDMA rule, that, here is the basic requirement. You can add whatever you want to it.

So now I am dealing with 50 different egos of states, if you will, and 50 different requirements that could essentially be the same if the states are not being advised by the FDA on what your requirements are. And that is a concern again. I have a pedigree staff that just monitors the state requirements and the differences.

MR. BERNSTEIN: It is getting a little bit

off the subject, but thank you. We will take it into consideration. Anybody else have any comments or questions that they want to raise? Please.

MS. ROBINSON: Hello. My name is Donna Robinson. I am a regulatory professional at Ranbaxy. I just wanted to touch on the topic of contract manufacture. I wanted the agency to put to note that a generic pharmaceutical company is required to file a supplement, a prior-approval supplement if it is a contract manufacturer. Therefore, the system is in place to look at is this formulation the same. Is the equipment the same.

Therefore, the need to change the NDC code may not be needed because you still have that same type of controls. I believe the agency is trying to do what it tries to force the pharmaceutical companies to do and that is to continue to look at our systems and to continue to implement better systems.

If it is to implement better systems, I think, in changing the NDC code for this contract

manufacturer, this contract manufacturer adds different things for us more to look at and increases the chance of error.

If it is a prior-approval supplement and you have shown that it is the same formulation, it is the same product and it is manufactured in India, Switzerland and it is the same formulation.

I ask the agency to consider that it be the same NDC code.

In terms of recalls, you can still track it by the lot number, which identifies that lot number being manufactured on such-and-such a date at such-and-such a time and by what place it was manufactured. Therefore, it can be recalled.

If it is a recall on a formulation, that whole product will be recalled. Therefore, it decreases--may decrease--the need to recall, in terms of having different NDC number codes.

DR. GARDNER: So are you suggesting that we carry lot-number information in listing?

MS. ROBINSON: That is not the suggestion, to carry it. But if the agency's concern is do you

have control. If you have a recall, can the FDA know what lot or where that product was made. You still can because, by that lot number, A,B,C,X,Y,Z, I can tell you, and I am sure every pharmaceutical company here or every company can tell you where it was made, who manufactured it, who packaged it, who handled it, who analyzed it. Therefore, you still have the same controls.

MR. BERNSTEIN: Thank you very much.

MS. McGAHAN: Good morning. I am Chris McGahan from Abraxis Pharmaceutical Products, Division of Abraxis Bioscience. I have a comment on regards to separate NDC number for each level of packaging.

The proposed ruling says that there will be a NDC number for the individual unit, the package and the shipper. Being a somewhat small company, we currently have one NDC number that encompasses this. If we were to have to go through and do a separate NDC number for each level, the number of man hours to change all of that labeling would be enormous for us.

We sell a package. We may sell a 2 ml vial packaged in 25 packaged in 50 in a shipper. We will give it a package code of 2 because that is its end unit. For us, this is just an easier way--we can keep track of it all the way through to our batch records and all of that. But, to ask for us to have three levels of NDC numbers for one product is a massive undertaking.

MR. LEVIN: So when you sign that level with No. 2, which was that--

MS. McGAHAN: That would be the package code. That was be for its a 2 ml vial. It would be a package 2 ml.

MR. LEVIN: If you have a number of them in one package, in one box?

MS. McGAHAN: It is just packaged as 25. It is then stated in the PIs and the SPL as its package size of being 25.

MR. LEVIN: That is what, then, you assign a number to that? The vial or the whole package?

MS. McGAHAN: To the vial only.

MR. LEVIN: Then, if you are packaging

different iterations--

MS. McGAHAN: Then that number will change. If our main package is--we pretty much package everything in 25s. If it changes, say, to a 10 and we have a 10 and a 25, the 25 will help the package code of 02 being the vial unit. The 10 pack will have a 10 because it is now a 10-pack.

MR. LEVIN: Okay. So a package of 25 2 ml vials and the package of 10 will have two different--

MS. McGAHAN: Yes.

MR. LEVIN: Then the trouble with adding a NDC at each--at the package and the vial, it is putting it on the package of the product, itself, or just coming up with the number?

MS. McGAHAN: It is not coming up with the number. It would be a matter of labeling for each component because currently, if our label, vial label, is sufficiently--holds all of the information, it will also be used as the tray label. It will be placed on the front of the tray. Then there is a separate diagraphed barcode label

that really has just the lot and XP and a barcode that goes on top of the tray.

If this were to be implemented, we would have to create a separate tray label for each of those trays and then another one for the shipper.

MR. LEVIN: So it is the labeling on each one of those components, not so much the number, itself.

MS. McGAHAN: No; not the number.

MR. LEVIN: The barcode right now, or the numbers on that outside package.

MS. McGAHAN: Yes.

DR. GARDNER: You talked about three levels. So there is the unit vial, which has its own NDC. Then you have boxes of 10 or 25 which would each have their own NDC number.

MS. McGAHAN: Currently, no.

DR. GARDNER: But then you said three levels. Then a box, a carton full of boxes, of 25?

MS. McGAHAN: Yes; the shipper.

DR. GARDNER: I am not sure we envisioned that third level. I think we definitely did

envision the second level.

MS. McGAHAN: That was just my interpretation of what I read, that it was the individual, the carton and the shipper level.

DR. GARDNER: You need to help us, in your comments, clarify those issues so we can decide exactly how to do that.

MS. McGAHAN: Okay. Thank you.

MR. BERNSTEIN: Thank you.

MR. NEWMAN: My name is Rick Newman with RnD Services. I want to bring up a topic I haven't heard talked about yet, at least publicly. Some of the companies I work with are pharmacy compounders who are not required, of course, to list as pharmacy compounders. But what we have found recently in doing some work in conjunction with FDA, we have put unique NDC numbers--we have voluntarily gotten an establishment listing regulation, so we have gotten our NDC numbers.

They are very unique for that compounded product because they can claim the diluent and sometimes maybe multiple actives, whatever it might

be. We put the NDC, barcoded it, and given it to the hospitals. It has become very useful in the hospital setting from a point-of-care perspective because then, when they scan the patients wrist I.D., and scan our drug, they can see that they are getting the right product, the right compounded pharmacy product into the right patient.

Now, because it contains multiple products and the rest of it, the way it is set up, according to the rule, there are a lot of issues. You can see around being multiple products and the rest of it. Now, we are just trying to figure out how we would comply or could we continue, if we did as John Gardner suggested, to suggest NDC number with our establishment listing. But we, of course, wouldn't have all the various labeling pieces that you would get with a branded product and the rest of it.

That is the issue we are trying to face and I was wondering if you guys had thought about that one yet.

MR. LEVIN: Do you currently list those

compounded products?

MR. NEWMAN: No; we do not list the compounded products. We have actually gotten direction from FDA because we have hundreds of them. We don't list them.

MR. LEVIN: So you just put an NDC number on there but don't list those products.

MR. NEWMAN: And they are not listed; yes.

MR. LEVIN: You would be interested in listing them?

MR. NEWMAN: Quite honestly, we would just as soon continue not to list them. That would make it easier for us and I would think easier for you because, basically, when a physician calls up and needs a new compound for that patient, we are talking about moving fairly quickly. The time constraint for that is an issue for us.

MR. LEVIN: I may have put it a different way. You would want to continue using the NDC.

MR. NEWMAN: Correct. We would not want, for example, for an inspector to come in and see our NDC numbers and say, oh, they are not listed

and you are misbranded in some way. That is the concern from the compliance point of view.

DR. GARDNER: These are pharmacy-compounded products that are patient-specific so they all have the patient's name of them.

MR. NEWMAN: Some do. Some don't. Some are anticipatory compounding. You can get to a whole--we can have a whole day on that one. But that is not--

DR. GARDNER: We don't want to get into that issue.

MR. NEWMAN: We don't want to go there.

DR. GARDNER: But if you have a patient-specific product that has a patient's name on it, you would want to use an NDC for that; is that what your question is?

MR. NEWMAN: Yes, because sometimes--just take something like oxytocin where it is compounded but it is for many--you leave space for a patient's name but you have got many patients coming in for labor and delivery in the hospital in any one day.

So you would still have that specific NDC number for that oxytocin at that concentration in that diluent--some hospitals like normal saline, et cetera, Ringer's lactate, whatever it might be.

But what is good about it, really, the advantage we see is that it does get you that traceability right to the patient and right back to us so there is a public-service aspect to it. It is just how do we fit it into the rules and the system.

MR. BERNSTEIN: Thank you.

MR. MIRABELL: I am Dave Mirabell, Director of Regulatory for Hollister Stier Laboratories. Hollister Stier is a manufacturer of allergenic extracts as well as a contract manufacturer of parenteral drugs and biologics.

Speaking regarding allergy extract, part of the business today, allergy extracts, generally speaking, have been exempt from NDC numbers. In many cases, about 10 generic numbers have handled the whole product line. By the whole product line, I mean that, under allergy or biologics, we have

650 different source materials under our BLAs.

That equates, in the product lines of sizes and formulations to well over 2,000 NDC numbers. In actual practice, my firm actively extracts and manufactures about 350 different source materials but that still relates to well over 1,000 unique NDC numbers.

That is just for those products that we would deem stock. The prior gentleman talked about custom formulations, custom manufactured products, that we would manufacture for specialists such as allergists or ENTs. Those are finite as to the combinations of allergens and dilutions and package sizes that might be related.

I have no idea what this industry will do regarding those products. I also want to relate that, probably unique to--most, 99 percent, of the allergy extracts are shipped directly to the specialist. They do not go into the normal distribution chains that most here probably relate to.

So I am just letting you know the

complications of this biological product line and, if we do move forward in trying to meet these rules in some regard, it will be a difficult adventure for the seven small business companies that are involved in this practice.

I also want to relate kind of a different situation. If you take 350 different allergens for NDC numbers, in one product form, that means one package insert, or one PPI, in this proposed system will relate. We will use the same PPI for those 350. So each of those NDC numbers we would file for that one formulation would use the same PPI. That relates to about six different PPIs we have in four different product forms.

Maybe if I can add one more thing on NDCs regarding diluents for allergenic extracts. Maybe I am bit confused about what I heard regarding different package sizes. Diluents for allergenic extracts--we have NDCs, but we relate them by size of the contents of the diluent. So, at 2.0 ml for a buffered saline with phenole, which is one of the products, we would have a 2.0, 4.0, 4.5, 9.0, 20,

30 and 50. We relate them all to the base product NDC number but under the package size is how we differentiate those.

Thank you.

MR. BERNSTEIN: Thank you. Any other comments? Otherwise, I think we can break for lunch. We are hoping to start again at 1:00 p.m. this afternoon with more speakers.

[Whereupon, at 11:55 p.m., the proceedings were recessed to be resumed at 1:00 p.m.]

A F T E R N O O N P R O C E E D I N G S

[1:00 p.m.]

MR. BERNSTEIN: Good afternoon everybody. I think we will try to keep moving along with the same kind of efficiency that we had this morning and go right to the afternoon speakers off the schedule agenda.

Public Speakers

MR. BERNSTEIN: The first speaker is Heidi Horn from Perrigo.

MS. HORN: Good afternoon. I'm Heidi Horn. I have worked in the Perrigo Regulatory Affairs Department for the last 17 years and have overseen the management of NDC-number assignment and drug listing for the last 16 years. In fact, Perrigo was the first company to propose and have accepted by FDA a 2658 form that could be completed electronically.

At the sake of dating myself, I remember when we were managing NDC numbers before they were used to track Medicaid reimbursement. So a lot has changed over the years but, yet, I think

improvement is still needed.

I would like to thank FDA for giving us this opportunity to speak today. I am also excited about the opportunity to improve not only the efficiency but also the accuracy of the NDC number system and use today's electronic technology to do so.

The Perrigo Company has been in business in 1876. Today it is a prescription, generic prescription, manufacturer as well as the nation's largest store-brand--also a term for private label--OTC drug manufacturer.

We manufacture 450 products for 45 private-label distributors, CVS, Walgreens, Rite-Aid, in a variety of different sizes. This results in 7,000 active NDC numbers.

The scope of Perrigo's product line requires Perrigo to provide and be responsible for a variety of different roles. We are a manufacturer. We are a labeler. We are repacker and we are a distributor. Each of these roles have given Perrigo the opportunity to gain valuable and

extensive knowledge into the management of NDCs. In addition, Perrigo participated in the e-drug-listing pilot program.

Since private-label distributor is a large part of my presentation, for clarification purposes, I would like to define what the private-label distributor is. In my mind, private label and store brand are synonymous. I believe that store brand does a better job of describing this business because every store has a name and that name is a large part of their marketing program.

The name is displayed on the building before you walk into the store to make a purchase.

The name is displayed on banners when you walk into the store. The name is on the name tag of the employees trying to help you out. The name is on the bag that holds your purchases as you walk out of the store and the most painful part of the shopping experience, it is on the receipt.

But the name is also on the front of the label as well as the back of the label and

signature line of the products that Perrigo manufactures. In other words, the private-label distributor is the retailer, CVS, Walgreens, Rite-Aid. They are not in the business of manufacturing and packaging products. They are in the business of retailing.

So who is responsible for the regulatory compliance of these private-label products? It is the private-label manufacturer that is responsible for the compliance of the product, not only with FDA regulations but with other governmental agency registrations.

Therefore, most private-label manufacturers are responsible and accountable for assigning NDC number and doing the drug listing for the private-label distributor. In fact, there are only private-label distributors that do business with Perrigo that assign their own NDC numbers and do their drug listing.

There are many reasons that Perrigo has gained knowledge and experience in managing NDC numbers. One is that the private-label

manufacturer is in the middle. What I mean by that is a private-label distributor gives the private-label manufacturer NDC-number information such as NDC-number format as well as the signature-line information.

Then it is the private-label manufacturer that takes that information, assigns the NDC number for the private-label distributor and then submits that information to FDA. If FDA has a question, they come back to private-label manufacturer, Perrigo, who, in turn, may or may not, depending upon the question, have to go back to the private-label distributor. Then we forward the information on to FDA.

So, really, Perrigo is in the middle of the relationship between the private-label distributor and FDA.

Secondly, questions, questions and more questions from the private-label distributor. What is the NDC number used for? Does everybody use the same NDC-number format? I don't understand. Who signs those NDC numbers? And, the most commonly

asked question, why can't I use NDC numbers on dietary supplements.

Secondly, education, education and education. Several of Perrigo's foreign buyers have encountered issues when importing products into the United States. Many of these issues are due to incorrect assignments of NDC number and/or lack of drug listing.

Perrigo gets involved, educations the importer, gets them the information they need so they, in turn, can get FDA the information they need to release the product in customs, or from FDA.

Because of Perrigo's relationship with FDA, and the private-label distributor, as well as the variety of roles it plays in the supply chain, Perrigo has found itself a place to ask questions and to give answers regarding NDC numbers.

My presentation today is going to focus on the complexities associated with the current and proposed NDC-number system and the respective volume of NDC numbers assigned.

There are several factors that drive NDC changes and add complexity. These are today's factors. One is acquisitions. But let me lay out a scenario for you, just a real-time scenario. XYZ private-label distributor assigns their NDC numbers and submits the NDC numbers to Perrigo to place on their art work.

Over the course of time, we noticed that the product-code number--now this is the number that is in the center of the NDC number after labeler code--that the product-code number was used on more than one product. In addition, they were assigning--they product-code number was used on more than one product.

In addition, they were assigning multiple product-code numbers to the same product. So we contacted them. We explained NDC-number assignment. They weren't very happy but we explained it to them and we recommended that they contact FDA.

Well, time went on. As time went on, they contacted us and they told us that they wanted to

change their NDC-number format. They wanted to go from 5,3,2 format to a 5,4,1 format. Once again, we gave them the CFR citation and we recommended that they contact FDA.

Well, as time went on, XYZ private-label distributor acquired another private-label distributor, private-label distributor ABC. XYZ said, what a wonderful opportunity for us to clean up our NDC-number system. So they chose to use the labeler code for ABC private-label distributor as the opportunity to clean up their NDC number and consequently used ABC labeler code with ABC signature line and XYZ signature line.

We tried to bring to their attention that that wasn't correct. There is a happy ending to this story. The happy ending is that they were, then, acquired by another private-label distributor who did understand the rules and regulations as it relates to NDC numbers and labeler codes. So acquisitions is one area that adds complexity to the current NDC-number system today.

Changes in signature lines; some

private-label distributors go through restructuring. This can also create changes to NDC number.

Product reformulations that involve active-ingredient changes is another area that can add a lot of complexity with today's NDC-number system. The nasal-decongestant category, I think, is a great example of this. In 2000, phenylpropanolamine was voluntarily removed from the marketplace. So cough-cold manufacturers replaced phenylpropanolamine with pseudoephedrine.

Well, pseudoephedrine was used in the production of methylamphetamine. Consequently, all pseudoephedrine-containing products were removed from the retail shelf and placed behind the counter. Consequently, a lot of the pseudoephedrine-containing products were discontinued.

Well, in order to provide the consumer, who didn't want to use the assistance of a clerk or a pharmacist in order to obtain a nasal-decongestant product, cough-cold

manufacturers are introducing another nasal decongestant product which contains phenylephrine.

So, phenylpropanolamine, pseudoephedrine, phenylephrine; all these changes have created changes in NDC numbers not only for one company, one product, but for all products containing those active ingredients for all distributors containing those active ingredients.

Lastly, a private-label distributor changes vendors. Due to pricing, product supply and product-offering considerations, private-label distributors will switch from one private-label manufacturer to another private-label manufacturer.

When Perrigo was given the new business from private-label distributor--we call it takeaway business--from a competitor, we will assign that product a new NDC number and the former supplier will have to then delist it. So private-label distributors changing vendors do add additional complexity to the system.

What I would like to do is I would like to walk through a supply-chain scenario. This is a

present-day supply-chain scenario. Where I would like to focus is on the private-label distributor here at the bottom.

This is a product. It is a soft-gel product. This soft-gel product is supplied to Perrigo from Supplier A and well as from Supplier B. In addition to that, we have a soft-gel product packaged into blisters at a contract packager as well as an in-house packager.

All of these parts and pieces come back to Patent Office and the blister strip is packaged into a carton at Perrigo and then distributed to the private labeler.

So we have Supplier A can use contract packager. Supplier A can use in-house packagers. Supplier B can use contract packagers. Supplier B can use in-house packager. Both get sent to Perrigo for cartoning and then it is shipped to the private-label distributor. This today results in one NDC number.

Based on our earlier conversation today, I do want to say that it is the lot number that gives

us traceability of that finished good back to whether it was packaged at the contract packager or packaged with Supplier A or Supplier B material. So there is a mechanism in place in order to track which supply chain that product went down.

So let's say Supplier A shuts down their plant. If supplier A shuts down their plant, what impact does that have on the NDC number of the private-label distributor? None.

Okay. Or the contract packager decides to bring in new equipment and cannot package for us for a period of time so all of our packaging must be done in-house. What impact does that today have on the private-label distributor's NDC number? None.

But if the private-label distributor acquires somebody or goes through an acquisition, that results in a new NDC number. If the private-label distribution decides to source the products from another private-label manufacturer, that results in one NDC number and if the regulatory status of active ingredients changes,

that results in a new NDC number.

The reason I reiterate those points is because, if you look at the commonality between those points, it is actually the marketplace that is driving changes to NDC numbers today, those things that happen after the finished goods are completed.

So, next scenario. Added complexities with the proposed rule. Added complexities with the proposed rule are driven by supply-chain scenarios. These supply-chain scenarios are those events that need to occur in order to develop the finished goods.

So, with the proposed rule, the changes are being driven by the supply chain not necessarily by the marketplace. These are changes in inactive-ingredient change in manufacturers and changes in contract packagers.

So we will take the same supply-chain scenario that we had previously. Okay. So Supplier A can use either a contract packager or in-house packager. Supplier B can use a contract

packager or in-house packager. It results in four different supply chains, all four, and four data NDC numbers, all four, one private-label distributor, one product, one size.

So let me make sure I am getting this across. We have four supply chains. Supplier A contract packager, Supplier A in-house packager, Supplier B contract packager, Supplier B in-house packager. This is for one product, for one size, for one private-label distributor.

It results in four times the labeling, one for each private-label distributor, and it results in four NDC numbers. But it is for one product for one size for one private-label distributor.

AUDIENCE: I have a question of clarification. Are Supplier A and Supplier B the same company, or are they two separate companies?

MS. HORN: Supplier A and Supplier B are two separate companies.

Due to the volume of labeling and NDC numbers, efficiency becomes a concern since Perrigo must carry four times the inventory. In addition,

it means that Perrigo and FDA will need to manage four times the NDC numbers, not to mention the confusion that it will cause the private-label distributor.

But, hang on. Maybe there is a different way to manage this. Let's reduce the complexity by supplying some customers with Supplier A's product and the remaining customers with Supplier B's product. Then Perrigo is carrying half the inventory for each customer--excuse me, private-label distributor--and FDA and Perrigo are managing half the NDC numbers.

I think the idea has got merit. But, for some unknown reason, Supplier A has decided not to service Perrigo. Perrigo must find another supplier, Supplier C. Because Perrigo begins to source product from Supplier C, new NDC numbers need to be assigned requiring new labeling. New labeling. It takes five months to create the new label. Five months. So it is at least five months that I am not serving the private-label distributor.

Also, in addition to that, the consumer. Will they have product that they need, not to mention more NDC-number changes. So I think I want to go back and carry four times the inventory or four times the NDC numbers so then I guarantee product supply.

Okay. That's all right. So the equipment at the contract packager now needs to be changed and replaced. Perrigo needs to solely rely on in-house packaging but the capacity of Perrigo isn't great enough in order to supply all the needs of the private-label distributors.

What? More challenges? This will give the private-label distributor cause to change suppliers. That means changing the private-label manufacturer. Perrigo will lose the business to another private-label manufacturer. More NDC-number changes, less business for Perrigo. Neither of us benefit.

Oh, no. The incorrect label is placed on a product produced from a different supply chain. Supplier A contract-packager label is placed on a

product actually manufactured by Supplier B and in-house packaged. Although the label information will allow the consumer to use the product safely and effectively, the product is misbranded.

We will need to rework the product and correct the labeling. What would that do to supply? What will that do to cost?

The proposed supply-chain criteria to change NDCs coupled with today's market-driven changes to NDCs is not only increasing the complexity of the system but is also increasing the volume of NDC numbers.

So let's compare the current process to the proposed process. On average, Perrigo has 30 private label distributors carrying three size codes per product. It is 90 NDC numbers to manage in the current process. In the proposed process, that is 360 NDC numbers to manage.

The current process. NDC-number changes are driven by the marketplace wherein the process, these NDC-number changes are driven not only by the marketplace but also by the supply chain changes.

Private-label manufacturers carrying one label per product per private-label distributor per package size versus multiple labels for one product per private-label distributor for one size.

What about the potential for mix-up, misbranding? In addition; able to react to product-supply needs to prevent retail shortages in the current process. The proposed process; unable to react to product-supply needs resulting in retail shortages.

Last, to do a label conversion in the current process costs--just to change the labeling--\$90,000. In the proposed process, it will cost approximately \$360,000. This difference, probably more than likely, will be passed on the consumer.

So why did I want to focus on private-label distributors? Because the NDC number associated with the private-label distributors will change not only with market changes, as in the current process, but also with supply changes as in the proposed process. This will dramatically

increase the volume of NDC-number changes and consequently the cost of the providing these products to the consumer.

So what is my real concern? Increased volume and increased complexity will increase the possibility for error when the objective is to make the NDC-number system more accurate.

Recommendations. Our recommendations are based on two objectives; improving the accuracy of the NDC-number system and maintaining that level of accuracy and, secondly, improving efficiency of submitting and maintaining NDC-number format.

I am asked to stop, but I would like to run through my recommendations, if that is okay. It probably won't take me more than a couple of minutes. Objections? Okay. Thank you very much.

First, maintain the current rules of assigning NDC numbers. Before we attempt to manage a system more complex than we have today, let's try to improve the accuracy of the current system and maintain that level of accuracy for a period of time. Increasing the level of complexity will

potentially double the number of NDC numbers. It will be difficult, with this larger volume of NDC numbers, to identify which aspects of the system are causing the problems and which aspects of the system are actually providing the efficacy.

Secondly, remove the ability of private-label distributors to assign NDC numbers and drug lists. The private-label manufacturers are, for the most part, managing NDC-number assignment and drug-listing responsibilities for private-label distributors today. Remove that variable.

Third, implement electronic drug listing.

Reducing the number of times the same information has to be processed will reduce the chance of error. If the manufacturers are allowed to input the information directly into the database or work-in-process site, FDA personnel would only need to check the accuracy and do minimal data entry saving FDA time and improving efficiency.

The electronic process of obtaining a food-facility license is fast and efficient. My

hope is for the same or similar outcome for the drug listing.

Last, invest in education regarding the current requirements. Many of the inaccuracies generated by the current system can be overcome with education and clarification. Perrigo has experienced this with private-label distributors. Offer FDA-led classes or issue guidance documents.

The guidance documents are an excellent tool toward communication and education.

The guidance document that was used in response to the Food Labeling and Consumer Protection Act has been an awesome resource. I know that it has been issued several times over the last year. The question-and-answer format used in that guidance document is very effective.

Then that will give you a tool, also, that if further clarification is needed, like, no, you can't put NDC numbers on dietary supplements, mentioned four or five times, then you can do that.

I am encouraging that.

I am confident that the combination of

these four points will result in a more efficient and accurate NDC-number system. Once this has been accomplished, then let's sit down and discuss additional changes to the NDC-number system.

I have one last point. At the request of FDA, several years ago, FDA asked Perrigo if they would drug-list their products on a quarterly basis, not a biannual basis. Perrigo and FDA have tried to work together, due to the volume of our drug listings, to come up with different means of meeting this objective and meeting this requirement efficiently and accurately.

What I am hoping is that Perrigo can work with FDA in looking at what ideas and suggestions in using our knowledge and experience to do the same here in the future.

Thank you.

MR. BERNSTEIN: Thank you. I would offer an opportunity for follow-up questions if anybody on the panel has any.

MR. LEVIN: I have a question. On your present-day, let's say you change Supplier B and

are now using Supplier C, no change in the NDC number.

MS. HORN: Yes.

MR. LEVIN: So, really, at the top of this is the private-label manufacturer.

MS. HORN: No. Actually, in those particular--

MR. LEVIN: They are controlling the whole thing.

MS. HORN: Oh; correct. We are controlling the whole thing.

MR. LEVIN: So you are at the top there. You have these suppliers that you contract with. This is the contract and you are contracting with this packager.

MS. HORN: I want to add one point of clarification. Actually, Supplier A and Supplier B have a product. It is a soft-gel product--Perrigo doesn't have soft-gel technology--that they offer to a variety of different manufacturers and packagers in the industry. So it is really Supplier A's and Supplier B's product. They fill

out the 2657 form for the product.

Then we purchase that product from them. We obtain the information from them in order to create our labeling and do our quality-check systems.

MR. LEVIN: And list their products.

MS. HORN: Right. We are not going to them and saying, will you please manufacture us a soft-gel product that contains X, Y and Z active ingredients. They already offer for sale a soft-gel product with X, Y and Z active ingredients.

There is a difference. I think it is important to discuss this difference because I think, through our trade-association meetings, there is confusion as it relates to what is a private-label distributor and what is a contract manufacturer. Yet I think Supplier A and Supplier B as yet a third category.

If I am a branded company and I have a product, I may go to another manufacturer and give them specifications. Here is my formula. Here are

my specifications. I want you to manufacturer that for me. That is what I consider to be a contract manufacturer.

Private-label distributor, as I explained in my presentation, is a retailer. Then, yet, there is what I am calling Supplier A and Supplier B. These are people in the industry that have the technology that they create their own products and they offer for sale their own product other manufacturers or distributors.

MR. LEVIN: Don't their products meet your specifications? They are just off-the-shelf that they meet your specifications?

MS. HORN: They meet our need from the standpoint that they contain the active ingredients that we are looking for. We are not going to them and saying, please create us this product.

MR. LEVIN: But, if you did, would you get the same product?

MS. HORN: Yes; I would. I guess the difference is this. It is who is driving the bus. In the case of Supplier A and Supplier B, Supplier

A and Supplier B and driving the bus. They are out there trying to sell their products.

In the case of the contract manufacturer, it is branded product that is driving the bus. They are seeking out a manufacturer to do it. Those two scenarios, in my mind, are different.

MR. LEVIN: Then, by keeping the one NDC number, you are controlling the whole--

MS. HORN: We are controlling the supply chain and creating a finished product; correct. Yes; we are.

DR. GARDNER: You said here that you track those through the lot number. You track the supply chain through the lot number.

MS. HORN: Yes.

DR. GARDNER: Do you print the lot number on the label?

MS. HORN: Yes.

DR. GARDNER: Explain. Is there a difference between printing the lot number on the label than printing these four NDC numbers on the label that would also track the supply chain?

MS. HORN: The difference is a lot number is placed on the finished labeling component after the product is packaged. The NDC number is placed on the labeling component before the labeling component is printed. So that creates quite the dilemma.

DR. GARDNER: You couldn't do it after?

MS. HORN: At the moment, no.

DR. GARDNER: I mean, if it is a non-barcoded issue.

MS. HORN: At the moment; no.

MR. LEVIN: I have another question. Go back to Supplier A and Supplier B. They list their products. They are doing this. If they were under contract, then they would not list those products?

MS. HORN: No; I think they would still list those products.

MR. LEVIN: So they would still list them whether it is contract or not.

MS. HORN: Yes.

MR. LEVIN: One is that they are doing it on their own versus that you--proactively--versus

you are getting them.

MS. HORN: I think, in some cases, they would proactively do it in either situation. There is a check and balance between the person asking the manufacturer to manufacture the product and the manufacturer doing it. There is a check and balance.

MR. LEVIN: I am trying to look at the differences between these suppliers in this situation and the contract.

MR. BERNSTEIN: Thank you very much.

MS. HORN: Thank you.

MR. BERNSTEIN: I realize that we are running a little behind now. There is some extra time built in--it is kind of like an airline schedule, there is some extra time built into some of the intervals between speakers. We would be able to pick that back up.

Next up is Madeline Palla from the Animal Health Institute.

MS. PALLA: My name is Madeline Palla. I am the Manager of Regulatory Affairs for the Animal

Health Institute. AHI is a national trade association representing manufacturers for animal-health products, pharmaceuticals, biological products and feed additives used in modern food production and the medicines that keep livestock and pets healthy.

AHI member companies represent the majority of animal pharmaceuticals and animal insecticides as well as serving a significant segment of the world market. As such, we have a tremendous interest in the development of policy affecting requirements for foreign and domestic-establishment registration and listing for animal drugs.

The FDA's effort to implement an electronic-establishment regulation and drug-listing system are to be commended. Members of AHI, however, feel the impact of the proposed rule on many aspects of the animal-health industry has not been given full consideration in the development of the regulation.

Implications for animal-drug sponsors

include financial system, process and resource ramifications. With respect to the National Drug Code portion of the proposed rule, we raise the following issues.

One, assignment of an NDC number. The way the proposed regulation reads, the appropriate NDC number is the NDC number that the FDA has assigned to the last manufacturer, repacker or relabeler or private-label distributor responsible for the drug immediately before it is received by the wholesaler or retailer.

The animal-health industry currently uses the sponsor code as the labeler-code portion of the NDC number even if the sponsor does not manufacture the drug product. The proposed rule appears to take away an enormous amount of control from the entity with the most vested interest in the process, which is the drug sponsor.

The definition of a drug sponsor is used in these comments as the owner of the drug application. However, they do not always manufacture the drug. For example, many of the

drugs are told[?] manufactured for the sponsor.

MR. LEVIN: Contract manufacturing.

MS. PALLA: If less sponsor involvement is not the proposed rule's intent, the manufacturer definition needs to incorporate the sponsor. If a drug has an application and, therefore, a sponsor, the drug sponsor wants to retain the ability to drug list.

Two, implementation of the NDC number changes. FDA is proposing that the electronic drug registration and listing system be used to enter and update all NDC-number information as well as all registration and listing information no later than 9 months after the effective date of the final rule.

An overview of the proposed electronic-system requirements should be available prior to the finalization of the rule. It is critical that companies be able to assess their ability to submit information prior to the rule coming into effect. If the FDA system only accepts structured product labeling, the animal-health

industry is at a severe disadvantage as currently SPL is not required for animal drugs.

Clarification is needed as to whether the animal-health industry will have to drug-list all of their products again or if there will be a migration of the data to the CDER database.

Currently, if you go on line to look up NDC numbers on FDA's website, only CDER products NDC numbers are available. AHI would like to know if FDA intends to create one combined system for CDER and CVM.

Three, revision of an NDC number. The animal-drug industry will incur significant additional costs with the revision of an NDC number. To put the financial burden in perspective the animal-drug industry's total pharmaceutical sales for 2005 was estimated to be approximate \$3.9 billion compared to the human pharmaceutical industry's estimated sales of approximately \$164 billion.

For example, there is significant cost to industry to change a product label including

changes to the printing plate for the label, existing inventory that may no longer be used after the implementation date, cost of production of new labels, time and resources used to change the labels.

AHI would like to know if the economic impact to the animal-drug sponsors has been taken into account while writing the proposed rule as well as the potential effect of costs incurred by the industry raising the product prices for the consumer.

Our fourth concern, the requirement to have the NDC number in the barcode. There are several significant NDC issues raised as a result of present barcoding practices. Some segments of the animal-health industry currently utilize UPC barcodes on their labeling. GS1 issues the barcode owner's I.D. based on the FDA labeler code. Therefore, a similar numbering system is used for nonregulated products with UPCs.

Potentially, the NDC assigned by FDA could duplicate a code already assigned as a UPC. This

impacts all layers of the supply chain down to retail outlet. If a UPC were required, the inventory costs would be substantial. The animal-health industry should be exempt from the requirement to include the NDC on all labels with barcodes as it will be a great expense providing no apparent benefit to the health and safety of animals.

This requirement would present great difficulties in cases where other information is barcoded for manufacturing control. It is also important to note that changing the barcoding system does not only affect that drug sponsors, the manufacturers, but it will be a costly change for distributors that use the barcode data for their inventory and sales records.

It will require change to their electronic tracking systems and significant employee hours to incorporate the changes for multiple products.

I do have one last point after listening to several of the speakers today and what the NDC code is used for in human-health products, it seems

to me that a lot of it is to match the drug to the patient in the hospital or to make sure they are getting the right dose, the right drug, and then also used for Medicare rebates. The animal-health industry does not have a need for tracking these same things.

I very much appreciate the opportunity to speak today. If there are questions or clarification from the panel, I would invite some of the Animal Health Institute members that are in the audience to assist me in answering those questions.

MR. BERNSTEIN: Any follow-up questions from the panel? Thank you very much.

Next up is Mark Meteyer, President and CEO of the Compressed Gas Association.

MR. METEYER: Thank you very much. My name is Mark Meteyer. I am President and CEO of the Compressed Gas Association. CGA represents over 130 members. These are industrial and medical-gas companies involved in all types of gases including medical gases as well as the

equipment producers. We are a standards-development association. We have been in the business of developing safety standards for over 93 years.

First, I want to thank FDA for extending the comment period. I think it is very useful to have this dialogue and it gives us additional opportunity to fully analyze the impact of the rule.

I also want to thank you for the opportunity to comment today on the proposed rule of the National Drug Code System. The Compressed Gas Association and the Gases and Welding Distributor Association--I will be speaking on behalf of both of them today--represent over 1,000 pharmaceutical manufacturing locations that may be affected by this proposed rule.

The CGA and GAWDA understand the agency's objectives to improve patient safety and the timeliness and accuracy of traceability. However, it does not appear that agency considered the unique aspects of the medical-gases industry when

estimating the effect of new requirements on industry.

For instance, traditional pharmaceutical packages are typically single-use medical-gas packages that are re-used for decades, are refilled in different locations within the same company and, under current FDA regulations, only require a new drug-product label when the existing label is damaged.

The proposed rule will require that the drug-product label include the NDC code that is specific to the filling location, package type and size. This will require a significant increase in drug-product-label replacement and the time and effort needed to properly control the label inventory. The agency has proposed a regulation that would significantly increase the complexity of medical-gas-industry compliance. The proposed regulation would also result in unintended consequences that are at odds with the stated objectives.

The following points will explain how the

proposed rule will increase the likelihood of unintentional misbranding, put patient safety at risk, cause hardship on the industry without achieving the stated objectives and ultimately may limit the availability of medical gases in some areas of the U.S.

Present industry practice for each company is to have one product label for each product type.

Under the current proposal, a company could have over 40,000 substantially similar labels for a single product and require different labels to be affixed to cylinders in the same batch or lot number.

This increased activity of placement of substantially similar labels logically multiplies the potential for product misidentification contrary to the agency's stated objective. In addition, for our industry segment, there is no obvious advantage to including package size or package material in the NDC code.

We do not believe that the cost of compliance was evident to the agency when it

developed the proposal. The increased costs associated with labeling activities are substantial. For example, a 700 percent increase in label replacement. This would amount to an \$80 million investment in the first year and \$10 million in each subsequent year for oxygen alone, smaller runs of multiple labels with higher printing costs per label, increased receipt, inspection and release effort and documentation, increased storage requirements to segregate label types, increased controls to have multiple labels available per batch run.

We believe that the proposed rule may provide marginal improvement and traceability for medical gases. However, it provides no improvement in traceability for a large segment of the medical-gas suppliers.

For instance, the proposed regulation fails to address the existing situation where it is common practice for unregistered entities such as pharmacies, hospitals, clinics and public-health agencies including emergency responders and fire

stations to refill cylinders bearing the labels affixed by the previous gas manufacturer.

Therefore, the intent of the regulation is not achieved in that the agency will not be able to identify the actual manufacturer based on the NDC code when the product is manufactured by one of these unregistered entities.

There are potential implications for patient safety with this new system. Under the proposed rule, the FDA must assign a new NDC code with the manufacturer, repacker or relabeler for every new product and packaging combination or combinations that are considered discontinued and need to be provided again.

In addition, a private-label distributor must go through their supplier for an NDC code for every new product-packaging combination. This could result in significant delays before an NDC is assigned resulting in patients not receiving needed drugs in a timely fashion especially in disaster-recovery situations; for example, the area affected by Hurricane Katrina.

Similar situations occur on a smaller scale in the oxygen-distribution chain and it is not clear that the agency and our label vendors have the resources to provide timely support to help industry assure that patients receive their prescribed oxygen.

Nearly 60 percent of the medical-gas supply chain is serviced by independent medical-gas manufacturers many of which are small businesses. Imposing these requirements and associated costs on small firms, especially since these changes will not provide a commensurate improvement in the safety and security of the medical-gas supply chain could result in many of the firms exiting the medical-gas business.

The likely impact of this would be to significantly limit the availability of medical gases in many areas of the U.S.

In summary, for medical gases, this proposed rule will cause increased errors in misbranding, increased costs with questionable benefit regarding traceability and increased risk

to patients due to delays in supply and potential unavailability of life-sustaining medical gases.

CGA will be submitting more detailed written comment prior to the January 26th deadline.

We appreciate the opportunity to address the proposed rule and look forward to working with FDA to address our concerns.

Thank you.

MR. BERNSTEIN: Thank you. Any follow up?
Thank you very much.

John Willenbrock

MR. WILLENBROCK: Good afternoon. My name is John Willenbrock. I am President of Gas Regs Incorporated and am representing AA Homecare as its Vice Chairman of our Medical Gases Committee.

The American Association for Homecare, AA Homecare, would like to thank the agency for providing us with the opportunity to comment on the proposed changes to the NDC system. We will be submitting our comments on these and other aspects of the proposed registration and listing rule by January 26.

AA Homecare represents approximately 700 healthcare providers with approximately 4,000 locations nationwide. These providers include manufacturers, suppliers and home-health agencies who furnish healthcare services and durable medical equipment to hundreds of thousands of Medicare and other government and private payer beneficiaries.

A significant portion of our members provide medical gases, primarily oxygen, to respiratory-care patients at their residences. Although we support the agency objectives to improve patient safety and product traceability, we are not sure the proposed changes will achieve those objectives in the case of medical oxygen.

Our comments today are limited to the proposed requirement to have the appropriate human readable NDC number appear on the drug label and the impact that that will have on both our members who manufacturer and distribute medical oxygen and on the patients we serve.

AA Homecare fully supports the comments just made by the Compressed Gas Association and the

Gases and Welding Distributors Association. Like CGA and GAWDA, many AA Homecare members fill and refill their own oxygen cylinders. The same cost-benefits concerns that these associations have raised regarding their members and the customers that they serve apply to our members and our patients as well.

We are concerned about the potential mix-up of labels at each filling location when the only differentiator between oxygen labels would be the container size and type theoretically differentiated only by one or two numbers or possibly letters in a 10- or 11-digit NDC. Unlike most pharmaceuticals, different size and types of containers can be filled or refilled at the same time on the same high-pressure filling line because container size is not dose-specific and container material such as steel or aluminum does not impact drug-product quality and safety.

Where only one compliant label is currently required, the proposed rule would require multiple unique labels for each size cylinder.

Until this morning, when a slight clarification was made, this could also be compounded by the number of different filling locations, in some cases several hundreds within the same company.

Similar concerns exist for liquid oxygen units with different capacities filled at homecare facilities and at patients' homes. Where one label currently suffices, multiple labels would be needed.

The agency acknowledged the fact that container differentiation was not necessarily a patient-safety issue when it exempted medical gases from the barcoding requirement a few years ago. In addition to those concerns, many of our member companies own their own cylinders labeled with an oxygen USP label bearing their company name preceded by the words, "distributed by."

They currently have those labeled cylinders legally filled by several firms often in different parts of the country. Under both the current and proposed rules, these firms would be considered private-label distributors. However,

under the proposal, they would not be permitted to obtain their own NDC number as they currently do.

The proposed rule would require the filling firm to obtain an NDC code that is unique at that filling location increasing costs and causing unnecessary delays in providing patients with their needed oxygen.

For example, a patient that travels to Florida from New York with an oxygen cylinder that was contractually filled by one of our members in New York using the "distributed by" statement could not legally be filled by that member's contracted firm in Florida without a change in label.

How long will it take us to obtain an NDC labeler-code number, obtain a new label from our label manufacturer, have that manufacturer relabel the cylinder and, finally, provide it to the patient. We question what additional safety is gained from this proposed requirement.

The requirement would also create a barrier to changing medical oxygen suppliers not present today. Consideration would now need to be

given to the additional time necessary to obtain the new NDC number, the additional costs in time to have the new numbers printed, new labels printed, then the cost in time to have them replaced on all cylinders.

In some cases, the labels are placed under a coating to enhance label readability and prevent damage. To remove and reapply the coding with a new label will be cost-prohibitive. We also have concerns with how this proposal will impact our members and CMS as we wrestle with the new budget law requiring the transfer of container ownership from the home healthcare company to their patient once the patient has been on oxygen for 36 months.

In conclusion, we look forward to working with the agency to address these concerns and we invite the agency to contact us to answer any questions with what we have presented today or any concerns which you may have with our written comments.

Thank you.

MR. BERNSTEIN: Thank you. Any follow up?

Thank you very much.

Next up is Paul Larsen of the Consumer Healthcare Products Association.

MR. LARSEN: Good afternoon. My name is Paul Larsen and I am the associate general counsel of the Consumer Healthcare Products Association, or CHPA.

CHPA was founded in 1881 as a trade association representing manufacturers and distributors of non-prescription or over-the-counter medicines in dietary supplements in the United States. Our 65 active members account for over 90 percent of the OTC medicines used and trusted by Americans to treat their common everyday illnesses and conditions.

CHPA supports FDA's efforts to establish an interactive electronic establishment registration and drug-listing system. This technological advance can improve efficiency and aid in the detection of errors, omissions or other problems in registration and listing information.

To ensure a fully functioning system that

meets the goals of the agency and minimizes the impact of industry, CHPA would like to work with FDA in cooperation during this developmental phase.

We are, however, concerned about several changes that are being proposed to the NDC-number system that are intended to remedy certain perceived shortcomings in the system.

Our member companies have given us extensive feedback on these proposed changes. We will be addressing a subset of these concerns and offer solutions during today's meeting. We will also be submitting detailed written comments in the proposed rule in January.

CHPA encourages the step-wise approach that focuses first on the development of an electronic system that utilizes the exiting NDC-number system. CHPA further supports issuance of draft guidance in technical specification on the electronic submission of registration and listing information. We believe this approach will best serve FDA, the regulated community and ultimately the American consumer.

The first issue we would like to address concerns the proposal to designate the responsibility of assigned NDC numbers to FDA. CHPA and its member companies have several significant concerns with respect to this proposal. To begin, one of the agency's goals in designating the responsibility of assigning the NDC number to FDA is that manufacturers, repackers and relabelers will be able to obtain their NDC numbers quickly and, as a result, prepare product labels and marketing plans earlier.

But, as we at CHPA have learned from our member companies, FDA assignment of the NDC number, even if done electronically, will undo needed flexibility. For manufacturers of OTC monograph drugs, the proposal would cause a fundamental shift in the "go to market" structure of the monograph system.

Under this system, marketing preclearance of OTC drug products by FDA is not required if the standards of the applicable monograph are met. Having to obtain an NDC number from FDA in effect

subjects these products to a form of premarket review. Timely consumer access to these products could be negatively impacted especially in light of the fact that vast majority of OTC drugs on the market today are monograph-based.

Currently, NDC number are often assigned well in advance of the actual launch of the product, sometimes several years or more. At the time of assignment, formulas, packaging, imprint information and even the manufacturing site may not be fully known. Trade customers routinely request NDC numbers for products that are scheduled to launch but not yet in production.

The need for flexibility and providing early alerts of NDC numbers to trade channels may be affected by the requirement that FDA issue the NDC number because the information to request the number may not be available or is for a developmental product that is not yet final. Short-term promotional skews can also be adversely affected or, in certain cases, altogether halted due to the intervening step of FDA assignment.

FDA's proposal lacks a needed mechanism to change information in the NDC number application prior to the listing information being submitted. Any number of changes could occur at this stage of development, from a change to the proprietary product name to replacement of the preservative system system and the formulation based on stability data.

Under the proposal, if a product is changed after the request for an NDC number has been submitted, there could be multiple NDC-number requests and numbers for a drug prior to commercialization. The risk of confusion in product-launch delays in this situation would be high.

Similarly, if a product is changed after the product has been assigned an NDC number or reached the marketplace, the company's internal records, manufacturing and control documents in embedded universal code, or UPC, carrying the first issued NDC number would have to be revised. New labels and art work to reflect the updated NDC

number would have to be created and previously prepared labels may become obsolete.

The burden associated with these reworkings and increased inventories is substantial particularly for smaller companies with fewer resources. Again, the risk of confusion in product launch dates would be high.

It is also unclear what would become of an NDC number that is assigned to a particular product or dosage form that is never launched. Would a manufacturer, repacker, relabeler, be required to withdraw this information? A similar question arises with respect to a product that is changed after the request for an NDC number has been submitted. What becomes of this information?

Our member companies have also expressed concern with the requirement to consolidate labeler codes and the confidentiality of that information from products and and business relationships prior to launch.

Next, we would like to register our concern with the requirement that the information

to be submitted to obtain an NDC number includes inactive ingredients. Inactive-ingredient changes in a product, whether qualitative or quantitative, can occur before or after the product is launched for any number of reasons.

The inactive ingredient may be replaced because it is unavailable or has become too expensive or a new raw-material vendor may have acceptable specifications with no effect on the product that vary from those of the previous supplier.

Where a product has more than one manufacturing site, especially between a foreign and domestic site, there is a possibility that an inactive ingredient may be different but equal within the formula. Requiring inactive-ingredient information for assignment of NDC number runs counter to the FDA's sanctioned flexibility that permits overinclusive inactive-ingredient labeling.

In November, 2001, FDA determined, in response to citizen petitions, that overinclusive inactive ingredient labeling may be accomplished

consistent with the Federal Food Drug and Cosmetic Act by placing those ingredients that may or may not be contained in the OTC drug product in the inactive-ingredient listing with an asterisk placed next to those ingredients.

It is unclear whether the agency is now seeking to overturn this prior determination. Under the proposal, every time an inactive-ingredient change occurs, unless the approved U.S. application number is provided, a new NDC number from FDA would be required. This opens the NDC number to being changed many more times than it is subject to change under the current system.

It also opens the door to multiple NDC numbers being issued for the same product. This could result in unnecessary confusion and product-launch delays and, as previously noted, changing the NDC number is not an insignificant undertaking for documentation or related purposes.

We believe that existing regulatory and related requirements applicable to OTC drugs are

sufficient to address the agency's concerns for several reasons. First, monograph OTC drugs may only contain suitable inactive ingredients that are safe in the amounts administered and do not interfere with the efficacy of the drug product.

Second, the label of all OTC drug products must specify the identity of active and inactive ingredients. Third, the current labeling is required to be submitted to FDA at the time of drug listing.

The third issue we would like to address concerns the criteria for determining what constitutes the appropriate NDC number. The proposal segments the current definition of manufacturing into four functional types; manufacturer, repacker, relabeler and drug-product salvager. The private-label distributors are not included within this group.

Under the proposal. an entity that develops a new proprietary formula as part of its research and development for an OTC drug product and then utilizes a contract manufacturer, or

manufacturers, for commercial production of that drug product does not meet the definition of a manufacturer, repacker or relabeler or drug-product salvager or a private-label distributor.

This quagmire produces a troubling result.

The entity arguably with the most product knowledge is unable to obtain an NDC number and listed drug and, in effect, is classified as a private-label distributor which it is not.

The entity would essentially lose control of its own drug and the contract manufacturer would forcibly be delegated this authority. In the final rule, the definition of manufacturer should be expanded to include an entity that is a specification developer. Alternatively, the definitions and associated responsibilities should distinguish a distributor which might be the specification developer for a private-label distributor and allow the distributor to form its own drug listing.

As an addendum to our written comments, CHPA will be providing a list of scenarios not

unlike that which was presented by Perrigo earlier today to help illustrate the questions and complications including assignment of multiple NDC numbers to a single product that the proposed rule will generate.

The next issue we would like to address concerns the agency's proposal of a nine-month time frame for reviewing and updating the information in FDA's database for NDC numbers assigned to drugs before the effective date of the final rule.

In short, 9 months is an inadequate period of time to verify compliance. OTC drugs on the market today are expected to have an NDC number and, for some producers, the number of effective products will be in the hundreds, if not thousands, at the time of the effective date of the final rule.

The complexity of the proposal's NDC-number requirements also supports an extension.

Private-label distributors including specification developers will, under proposal, lack the authority to access drug-listing information and supply

needed reviews and updates. Thus, extensive information sharing, coordination and cross-checking between entities will be required and this effort will be time-intensive.

In addition, a product with multiple inactive ingredient combinations or other minor differences may lack an NDC number for each variation of the product. To trace and bring these products into compliance with the new regulation, in addition to adjusting internal records and documentation to enable the review and updates to occur, will take a considerable amount of time.

The impracticality of achieving compliance within the 9-month time frame is further suggested by the fact that information entered by FDA into its drug-listing database is, itself, not up to date. To our knowledge, the last such update for OTC drugs was in 2003. Until this body of information is current, a comprehensive review cannot occur.

To account for these factors, CHPA suggests that FDA extend the period of time to

review and update information on drugs listed before the effective date of the final rule.

Our written comments will also address the proposal to phase in the requirements with an NDC-number placement and appearance on OTC-drug labels over a seven-year period.

The final issue we would like to address concerns the proposal that human-readable NDC numbers appear on the labels in drugs with the prefix NDC. CHPA concurs with the industry feedback received by the Eastern Research Group as outlined in the preamble, that the new label requirements, as they apply in OTC "unit of use" levels such as blister packs may pose problems.

As noted by FDA, some packaging lines per "unit of use" OTC products not subject to the barcode might need to be retooled to accommodate human-readable NDC numbers and these modifications are expected to be fairly challenging.

Space on the label is also a concern, particularly for small and medium packages with limited label space. Professional promotional

samples fall into this category as well. Having both a barcode and a human-readable NDC number could mean going to a larger container with a larger label which raises issues of increased cost.

What alternative we would recommend is allowing the use of "N." This option would utilize less label space than NDC and would clearly signal the NDC number. Importantly, requiring the NDC number on secondary packaging may create additional burdens for the labeling of temporary skews such as promotional skews, 'buy one, get one,' or "bo-gos," where two or more immediate containers are repackaged into a single carton.

In this situation, each immediate container will have an open stock NDC number but the promotional skew may require another different NDC number as a different packaging configuration.

New immediate containers, rather than open stock, with this "bo-go" NDC number would be required or the open-stock immediate containers would need to be overlabeled.

In sum, CHPA believes mandatory inclusion

of the NDC number on the product label should not be required for OTC drug products especially those products that are skewed that do not require a barcode label.

MR. BERNSTEIN: Thank you. Any follow up?

MR. LARSEN: Just as a conclusion, I would thank FDA for the opportunity to present today. I would be happy to answer any questions.

MR. LEVIN: I have a question. For the time frame, you talk about the phase-in for the labels. What is the time frame for reviewing your NDCs.

MR. LARSEN: Are you talking about for the nine--well, there is nine-month time frame for reviewing existing NDC numbers. We don't think that will be adequate.

MR. LEVIN: So how much time do you think you will--

MR. LARSEN: We will address that in our written comments. We are still sorting out that issue.

MR. LEVIN: If the NDCs are listed in the

database--you are talking about that they are listed in the database and you are going to check and make sure that you have the NDC listed there.

MR. LARSEN: Right. I think that that would be part of what is included in reviewing and updating that information to ensure they are compliant. I think you would have to do it on an NDC-number-by-NDC-number basis because the issues could be different.

For example, under the proposal now, if there is an different inactive ingredient used in a different--per product, or there are inactive-ingredient changes, in that case, it would require a new NDC number for each of those changes and it can get very complex quickly.

DR. GARDNER: I think the issue is related--the timing issue might be related more to developing electronic labeling than actually reviewing information because the information would come directly from the electronic labeling. So could you address that in your comments?

MR. LARSEN: I think using the electronic

form would definitely enhance the review and update process because you would probably be able to more quickly identify if there were different inactive ingredients per product.

DR. GARDNER: What I am getting at is in submitted an electronic label that has ingredients in it and we are able--it is submitted in such a way that we can extract those and that is how we would want to do the listing, then the time isn't in reviewing what is in our database. It would be in reviewing what you put on those electronic labels. That is the issue.

Since the information in the database is going to come directly to the labels, transferring it from the old system isn't necessarily going to help.

MR. LARSEN: Okay. Thank you. We will address that in our comments as well.

MR. LEVIN: I have another question about inactive ingredients. So you use the inactive ingredients that you are allowed to use as far as the specification. In the label, itself, which

inactive ingredients do you supply? In the label, on the box, what inactive ingredients do you put on the label now?

MR. LARSEN: We want the label to accurately reflect what is in the product. Our member companies accurately list those or follow what is allowed under the current regulations. So I think it is what is captured in the product. We capture what is in the product.

MR. LEVIN: So if a product then changes, though, with the inactive ingredients, then you are proposing no change in the NDC.

MR. LARSEN: Correct. We do not believe that the inactive-ingredient information should be required to obtain an NDC number.

MR. LEVIN: Okay.

MR. BERNSTEIN: Thank you very much.

Next up is Wes Siegner from Hyman, Phelps and McNamara.

MR. SIEGNER: Good afternoon. I am from Hyman, Phelps and McNamara. We represent basically all of the different industry groups in one form or

another, individual clients mainly that are in the drug medical gas and other industries here.

I am not here actually speaking on behalf of those entities today. I am speaking on behalf of medical-foods and dietary-supplement interests so I have to be a little bit careful about not making anybody upset with me.

First, I wanted to start with some general comments. I see this proposed rule as having huge ramifications. I better understand those today after hearing other commenters speak about the specific aspects of the implications for their industry.

I think we all agree that there needs to be a change to the current system and shift away from a paper system to electronic system, but, in my view, the proposal goes far, far beyond that and needs to be rethought in many aspects.

In echoing Paul Larsen's comments about the OTC industry, I think that this proposal effectively if--it depends on how it is implemented but, as I understand it might be implemented, would

become a form of premarket approval for OTC drugs.

It would substantially, from a practical effect, have huge delays on introducing OTC drugs to the market.

I don't believe that some of the aspects of this system would be authorized by the statute because of the implications for that industry.

The other aspect and getting more directly to the point that I am here for today which is on behalf of medical foods and supplements, I am not going to argue that they are appropriately governed under the NDC system. However, the way the NDC system has been operating, as was pointed out, for decades, dietary supplements and medical foods have obtained NDC numbers and some of them depend on their marketing and some companies depend on the NDC numbers for their business because of reimbursement through those numbers.

Again, I am not saying that FDA ought to include those products within something that is called the National Drug Code, but, in considering the economic impacts of this rule, the agency, I

believe, is required to consider the impacts on reimbursement and public health and on small businesses. These are all issues that need to be looked into and considered. It may be necessary to set up a separate system for those regulated categories.

In closing, anybody who is a small business and feels that they are impacted by this, I recommend that you do get in touch with the Small Business Administration. They are very interested in hearing from small businesses and how regulations impact their day-to-day business.

Finally, I would recommend that the proposal be thoroughly reconsidered and simplified to address the electronic tracking issue and to remove a lot of the more far-reaching impacts of the proposal.

Thank you.

MR. BERNSTEIN: Thank you, Wes.

Next up is Carolyn D. Jones of Advamed. I think, after Ms. Jones, we will take the break a little bit late and extend the break to 2:30.

Was there a question?

MR. LEVIN: I have a question. Can you give me some more detail about, or are you going to provide more detail about, the dietary supplements and how they are affected by the--

MR. SIEGNER: We will be filing more detailed comments but it is effectively--I can't tell you what proportion of the industry, but there are doctors who prescribe supplements and medical foods regularly. I think it is mainly through the state systems. They are on lists and are reimbursed through state reimbursement programs and they rely on NDC numbers effectively to do that.

I know that wasn't an intent of FDA's, but that is effectively how the system is working for some of those products.

MR. LEVIN: Then with the proposed rule, the effects there?

MR. SIEGNER: The proposed rule specifically says that supplements were not intended to be covered under the previous regime and won't be included under this one. I guess it would

be possible to call this something other than the National Drug Code, and I am not necessarily saying that I agree with FDA that putting an NDC number on a dietary supplement is misbranding the product.

I think actually what some medical foods and supplements do is put the number on without the NDC letters, again not something that FDA would recommend or probably condone. But, again, that is how it is being done.

They need some kind of tracking system for reimbursement is the bottom line.

MR. LEVIN: So if there was a way that they could provide the information and do the NDC, that would be--is that something you will address in your comment?

MR. SIEGNER: I will cover that, but, yes; if there were some form, either within this system or another system, for them to have NDC numbers or NDC-like numbers, that would resolve the problem.

MR. BERNSTEIN: Thank you.

MS. JONES: Good afternoon. I am Carolyn Jones. I am Associate V.P. in the Technology and

Regulatory Affairs Department at Advamed. Advamed is a device trade association. I appreciate the opportunity today to present the device industry perspective on issues raised by CDER's changes to the NDC system, specifically, the proposed prohibitions against the use of the NDC number on non-drug products, which was just raised.

Compelling health and safety issues necessitate the continued use of NDC numbers on certain medical devices. While there are a number of medical devices that use NDC numbers, the most striking use is in diabetes-care devices which include blood-glucose meters, strips, lancing devices, lancets, syringes, pin needles, insulin-pump supplies and continuous monitoring products. Millions of patients use these products daily. Routinely dispensed through pharmacies, diabetes-care devices are uniquely identified with an NDC number consisting of an FDA-issued NDC number manufacturer's labeler code combined with a manufacturer-identified product code and package code.

In fact, NDC numbers have been used to identify blood-glucose monitoring devices for greater than 15 years and are an integral part of the healthcare system involved with diabetes management.

NDC numbers have three key roles in diabetes care. They are used to identify co-pay, to process insurance claims and they are used in patient safety and educational communications. We will discuss these aspects of their use.

NDC numbers are the key identifier for third-party reimbursement of diabetes-care products and other medical supplies throughout the United States. The reimbursement process for diabetes-care products is identical to prescription drugs. A pharmacy enters the NDC system into their pharmacy system to determine the coverage and copay for these medical-supply and diagnostic products.

The system communicates on line, real-time, to health-plan databases. These NDC numbers are submitted to multiple databanks to make available their on-line network which is subscribed

to by pharmacies, health plans, again just like prescription drugs.

NDC numbers are also used by pharmacies and healthcare plans to identify counterfeit product and prevent diversion. Elimination of the use of NDC numbers will result in dramatically higher out-of-pocket costs to patients for diabetes-care products as it would eliminate the existing system for coverage and co-payments.

Customer end-user complaints regarding new sudden impediments to obtaining these products would increase. The target of these complaints would range from retail pharmacies and other suppliers to state insurance commissioners.

Because the NDC number is an integral component of the healthcare system's use, access and processing of payments for diabetes-care products, prohibiting continued use of NDC numbers on these products will result in confusion that will disrupt patient access to these devices.

We believe that such a disruption would be costly both in terms of its monetary impact and in

terms of its undesired healthcare costs of patients which may be caused by interruptions in self care and primarily compliance with diabetes-management responsibilities.

FDA's estimate of the financial impact may not take into account the impact of non-drug products using NDC numbers in terms of the financial impact. Claims process for blood-glucose monitors alone with the NDC numbers are about \$2 billion annually. There are about 25 million transactions per year.

NDC numbers are printed on a product labeling, price lists, contracts, customer-support materials, training materials and sales-force materials. This will require creation of new packaging and patient materials, et cetera. Approximately \$350 million worth of existing inventory would have to be destroyed and replaced.

Further, if FDA requires medical-device manufacturers to move to a different coding system, every pharmacy computer-system health plan, computer-system and related on-line network being

used today would have to be reprogrammed.

As such, an activity would require the coordination of multiple parties, A move to a different coding system will require a lead time of five years or greater.

I am being told to stop here. Do you want me to continue?

MR. BERNSTEIN: If you could wrap it up.

MS. JONES: Well, one of the issues that we are looking at is the disruption in patient care. We understand that you would like to clean up your system and not have non-drug products on there, but what we would ask is that these types of products be allowed to continue to use the NDC code until such time as another system becomes available.

We understand that the device center is working on new device identifier. However, that immediately will not solve the problem as the associated systems and pharmacies and hospitals and so on will still have to develop programs in order to be able to recognize those systems.

In addition to their other roles, as I said, these systems, NDC numbers, are used by our manufacturers to decide where educational training and the like is needed for this diabetes-care equipment. So we will supplement our comments here today, since we had such a sort time, with written comments but we ask that you would allow the continued use until such time there is another system in place for these products.

MR. BERNSTEIN: Thank you very much. Any follow-up questions?

MR. LEVIN: I have a question. What about the health-related item code? How is that related to this?

MS. JONES: The health-related items code--now I tried to do some investigation on the use of that. According to my investigation, there are aspects in CDRH that are saying that they are no longer supporting that system. So that system is currently not in place for the diabetes care.

The other problem with switching to any other system is that, once FDA comes up with a UDI,

you want to the health-related code or UPC system, and they you are going to switch them to the UDI. We would just like to be able to maintain one system so that customers will only have to deal with one switch.

MR. LEVIN: Do you know anything about the health-related item code?

MS. JONES: I do know that some companies in the past have received those numbers and are using them. But, in the diabetes-care arena, there are not a large number of companies using the health-related code.

MR. BERNSTEIN: Thank you very much. We will break until 2:40.

[Break.]

MR. BERNSTEIN: We have two speakers left for the afternoon session. Then, after that, there is some time that has been allotted for open discussion again. The first speaker up is Pat Distler from the International Council for Commonality in Blood Bank Automation.

MS. DISTLER: Thank you. My name is Pat

Distler. I am from ICCBBA. I would like to suggest an alternative mechanism for labeling cellular-therapy products as opposed to using the NDC.

I would propose that we use something that is called ISBT 128. This is an international standard for the transfer of information that is associated with tissue, cellular-therapy and blood products. It provides for a globally unique donation identification numbering system, standardized product codes, internationally known data structures for barcoding and electronic data exchange.

One of the important features of ISBT 128 is that it is independent of the delivery mechanism so whether linear barcodes are used, which is what is common today, or two-dimensional barcodes, RIFD or electronic data interchange, it doesn't matter to the standard. This is a mechanism for delivering information.

I do work for ICCBBA. We used to be the International Council for Commonality in Blood

Blank Automation. Since our focus has changed to include tissues and cell therapy, ICCBBA has now become our name. We are a not-for-profit organization based in Virginia. That is where our corporation is. It develops and manages the ISBT 128 standard.

We do this by working with advisory groups, with experts in the field of cellular therapy, tissues and blood. We also interact with the other regulatory agencies and standard-setting organizations that are involved in these three fields.

ISBT 128, as a standard, has existed for ten years. It has been in use for ten years. For cellular therapy, there are a number of U.S. organizations using it today as well as a number of European cellular-therapy organizations. It is being used in cord banks throughout the world. That is probably where it sees its greatest usage is in cord banks.

It has been used in blood banks since 1997 in Europe. It is being implemented today in the

United States. There is a goal of May, 2008 for all U.S. blood banks to be using ISBT 128. Tissue; U.K. is using it currently in their National Health System and it is being evaluated for use in the U.S. by the American Association of Tissue Banks.

As far as cellular therapy goes, major international standard-setting organizations have committed to using ISBT 128. The organizations that have committed to this are listed on this slide.

Essentially, they represent all the major groups in North America and in Europe; the AABB, the American Society of Apheresis, American Society for Blood and Marrow Transplant, European Group for Blood and Marrow Transplant, Foundation for Accreditation of Cellular Therapy, International Society of Blood Transfusion, International Society for Cell Therapy, ISCT Europe and the Joint Accreditation Committee for ISCT and EMVT which is a European standard-setting organization.

These groups have all committed a representative to work with ICCBBA in further

developing the standard. As I said, it has been in use for ten years throughout the world, but, as we get more and more global, we are finding that it needs refinement. So these groups got together. Each sent a representative to do the work to ensure that this is universally acceptable.

The group has defined terminology and label designs. They will be publishing their two-years-worth of work for public comment in January and I will also mention that an FDA liaison has been invited to all the meetings.

The process by which ISBT 128 achieves international consensus is to first identify the experts in the field who can help us define the terms. Defining the terminology is very important and is the first step after the group gets together. Then the information is encoded into the computer-understandable terminology. We trade common databases that then can be used around the world and then we design the standardized label.

The common terminology is more difficult than it may seem. What to one group, a DLI is a

donor lymphocyte infusion or a donor leukocyte infusion. That is just within the United States. Then there has to be a consensus achieved worldwide.

Once the terms are selected, then they are defined and then these are published for broad input. The big thing is getting everybody on the same page so that everyone, whether they be in Shanghai, China or the United States, has the same meaning to that particular term.

The information is then encoded into data structures, as one of the speakers this morning alluded to. This is simply a string of characters that has meaning to a computer, that relates back to a database. The first two characters are a data identifier and so all the computer systems know the type of data, whether that be an identification number or a product code that is coming across. And then the actual data content.

The database, then, that supports these numbers is found on the ICCBBA website which is accessible to users as well as to regulatory and

standard-setting organizations. These reference tables are maintained and defined very carefully that if it is an S0005, that is a thawed HPC from bone marrow. This is the same definition, then, that everybody uses.

The last step is label design. This gets very, very particular. Exactly where every barcode appears is defined to the millimeter of where it needs to be. All the information that needs to be on the label is defined as occurring in a given location. As you can see, at this point, this is a very busy label.

That is actually one of our larger labels.

It is a 4-inch by 4-inch label. To put all the information that is important to both the clinician and to the facility that collected the product, it takes up most of the space. Now, cell-therapy products are subject to the barcode rule and you can see we are sort of running out of space on where we are going to put another barcode.

Why is it important, then, to put every little bit of information on exactly where those

barcodes appear. It is because you can get a foreign label, that this is an international standard. If you looked at this label--you probably can't read of a word of it. I certainly can't--but I do know what is going to be where.

Up here is the identification number of that, the lot number, if you will. This is the AB/O and Rh. Down here is the product code and down here is the expiration date.

If I scanned this into my computer system, my computer system is based on the same database as the one in China. So it will interpret this label into English for me allowing me to change the text into English text. If I didn't have the computer, it doesn't matter because the eye-readable information directly below the barcode can be compared back to that database and interpreted into English. So those codes would tell me how to interpret that particular label.

We have different size labels, as I said.

That is one of the larger one. We can get 1-inch by 3/4-inch labels or, as is used in cord banking,

about 1 3/4-inch by about 2-inch labels. Again, it is specified exactly what barcodes will appear and where they will appear depending on the size of the label.

Why is international standardization so important? These are very specific products. They are very carefully matched to the patient. The National Marrow Donor Program in the United States tells me that 39 percent of their products cross an international border. They are either coming in from another country or they are destined for another country.

These are unique products. Patients and donors are matched. When they are collected, most of them are collected with a very, very specific patient in mind. It is not a case of batch processing where there are multiple products in a given lot number. It is a 1-to-1 relationship most of the time.

A lot of information can be encoded using ISBT 128. One is the unique identifier including the manufacturer or the registry name, the product

code, the donation type, AB/O and Rh which is unique in this group for the importance of that information, whether or not the product is biohazard--in cell therapy is may be considered biohazard--the expiration date and time, collection date and time, special testing results, a donor identifier.

A donor identifier may not be important in blood transfusion where this system also works because that information is kept confidential. It is confidential in cell therapy. However, a physician may need to know that two products came from the same donor. So they may need to know not the identity of the donor but a mechanism to assure that it is all from the same donor. Also patient identification and date of birth.

What one of our identification numbers is is this. The first five characters are a facility identification code followed by a year. The facility identification code makes it unique worldwide. All countries, anyone who participates in this system is assigned a facility I.D. code.

The year allows it to be unique for every 100 years. Then a serial number followed by the flag characters. Flag characters are to identify where that particular unit number was read from, where the barcode was read. In the case of cellular therapy, you may be using the mother's sample to test the cord blood. You can identify that that particular sample came from the mother. It is related to that cord-blood collection but it came from the mother as opposed to the infant.

Then there is a check digit that can verify that the information, that the entire string of numbers, was entered into the computer system accurately if it was done through keyboard entry as opposed to scanning.

The facility identification number can also encode a donor registry. There is a statute that requires that the donor center that collected that be kept confidential because that can lead to the identification of the donor. So you cannot identify where that was collected on the label.

Because of that, you have to be able to

use the donor registry such as the National Marrow Donor Registry in Minnesota to identify that product. They, in turn, keep track of the collection facility.

The key to this, the database, as I have mentioned, is on the ICCBBA website. It is accessible to users and regulatory agencies so that you can identify exactly where that was collected or the registry that was responsible for its collection.

Once assigned, the donation identification tracking number doesn't change. This is important to cell therapy where being able to trace back to the donor who gave that product is very, very important. The only exception would be on a pooled product where multiple donors are pooled into a single product.

The information, then, appears beneath the barcode. The W number, in this case, identifies the center that collected that and that information would appear in text immediately beneath it. If another facility was involved in processing that

further, that would appear beneath that. With cell therapy, there are not multiple processors. There tend to be one or two.

As I had mentioned, there is also room for putting the AB/O group, the Rh, and whether or not it is considered a biohazard collection.

Moving on to ISBT 128 product codes, our products are defined in terms of their cellular content, the anticoagulant, the storage and other attributes. We do not include highly variable information. As I mentioned, cell-therapy products are very unique. They are patient-specific. >From the time they are collected, they are intended for one specific patient.

The active ingredients are the cells. The cells vary depending on who the donor is, what the donor cell count was. So we don't know ahead of time what that count is going to be. Indeed, because of the short dating on these products, 24, 48 hours, often the products are being shipped while we are still doing the laboratory work. That data will catch up with the product before it is

infused but it is not known at the time the product is labeled.

To try to assign codes based on the actual count would create way to many product codes for it to be manageable. The codes would have to be requested on a very urgent basis and we would lose the benefit of standardization. As I said, when that product from China comes in to the United States, we can scan that. That is only if it is in the ICFA database. If it is not there because it was assigned just as it was being shipped, that product cannot be translated once it gets into the United States.

We agree this information is useful and it does appear in eye-readable form, human-readable form, on the label but is not encoded into the computer code.

ICCBBA also reaches the patient's bedside because we do have data structures for patient identification and patient birth date to further identify the patient. Again because these products are meant for a specific patient, it becomes

important to tie it all the way to that patient.

So the advantages that I see of ISBT 128 over the NDC number was, one, it was designed for international use, overcoming language barriers. It provides collection processing or donor-registry I.D. The tracking number does not change during subsequent processing making it better traceable back to the donor.

It provides specific product information but it does not encode that information which is highly variable. The product codes are, therefore, able to be assigned in advance of need and be able to be circulated to anyone who might receive those products. It delivers safety to the patient bedside.

In summary, ISBT 128 is a very comprehensive system. It is designed specifically for cellular-therapy products. It is a proven system. It has been in use for over ten years in C.T. laboratories, tissue banks and blood banks worldwide. It is flexible enough to accommodate the technological advances that are prevalent in

cellular therapy and yet it is structured enough to maintain global standardization.

Thank you.

MR. BERNSTEIN: Is there any follow up?

MS. RICHARDSON: Do you see the ISBT and NDC as mutually exclusive?

MS. DISTLER: No; and I believe the next speaker will be addressing that. Perhaps not, but I don't think NDC number adds anything in the way of patient safety. Yet it becomes a burden to the industry because we are not using it now. The computer systems are not the pharmacies that will be handling these products. They are the blood banks and the transplantation services.

So it is not going to provide anything beneficial to the user. We are not using them today because we don't have licensed products.

MS. RICHARDSON: Would that be another data element that would go on the label presumably?

MS. DISTLER: It detracts. I mean, it is a redundancy.

MS. RICHARDSON: I'm sorry; I mean the

license number.

AUDIENCE: Can you repeat the question?

MS. RICHARDSON: I first asked whether you thought that the use of ISBT and the use of the NDC number or the placement of the NDC number on the label were seen as being mutually exclusive.

MS. DISTLER: No. The problem is, though, the international. If we have that extra barcode, it confuses. It has no purpose. No one is going to be able to read it because the computer systems are not designed in the laboratories to read the NDC number. So it may be useful to the FDA but I don't see where it is going to help the users, other than adding yet another thing to track.

It doesn't enhance patient safety and yet creates a burden for the industry.

MS. RICHARDSON: You are speaking of the barcode, the NDC number barcode.

MS. DISTLER: Yes, because it is another element to put on that label and sometimes it is a very small label.

MS. RICHARDSON: But what about the

eye-readable, human-readable, NDC number?

MS. DISTLER: I believe that will be addressed by the next speaker as far as how the industry views having to apply for that number on an urgent basis.

MR. LEVIN: I have a question, too. Who maintains the product codes?

MS. DISTLER: ICCBBA.

MR. LEVIN: The product codes--give me an example of a product that you--

MS. DISTLER: HVC cord blood.

MR. LEVIN: Then do you have any other components of that product that are--

MS. DISTLER: Yes; the temperature, the storage temperature, the anticoagulant and the volume of that product. Then there can be additional things. If it is CD4 enriched, that type of attribute or modifier.

MR. LEVIN: That is added to it.

MS. DISTLER: Right. The exact count is what we don't have.

MR. BERNSTEIN: Thank you.

MS. DISTLER: Thank you.

MR. BERNSTEIN: Next up is Allene Carr-Greer.

MS. CARR-GREER: Good afternoon. My name is Allene Carr-Greer. I work for AABB. Today I am speaking on behalf of a number of organizations.

AABB, America's Blood Centers, American Red Cross, American Society for Blood and Marrow Transplantation, Foundation for the Accreditation of Cellular Therapy, International Society for Cellular Therapies and National Marrow Donor Program wish to thank the Food and Drug Administration for the opportunity to speak at today's meeting. We support FDA's ongoing efforts to improve the safety of human drugs and biologic products.

Today, we will address the proposed requirement to implement the National Drug Code System for licensed human cells, tissues and cellular and tissue-based products, HCT/Ps, and, in particular, hematopoietic progenitor cells collected from peripheral or cord blood and

therapeutic cells as described in this attachment to my statement.

I have a list of these products for you now. In particular, they are not important to be called out today.

A requirement to implement the NDC system for these products will create a duplicate tracking system that will not provide increased patient safety but, in fact, may detract from the current level of patient safety. Today, and in comments to the docket for this proposed rule that are due by the end of January, we will provide justification for requesting that these products be exempt from any requirement to use the NDC system as outlined in 21 CFR Part 201, Subpart 201, and Part 207, Subparts C and D.

The exemption is requested under proposed 21 CFR Part 201, the one up on the slide right now.

In that, it is where the FDA does have an exemption lined out to the barcode requirement that, on their own initiative or in response to a request, the exemption request must document why

and, in our case, an alternative regulatory program or method of product use renders the barcode unnecessary for patient safety.

Again, we are speaking of the NDC number barcode.

It is our position that the NDC system is not a good fit for the products identified in this request and that manufacturers of the product and the companies receiving them for patient infusion and/or transplantation are already implementing a system that was developed specifically for them.

In support of our request for an exemption, we offer the following comments today; that NDC is a square peg for a round hole. Due to the biological nature of the products and the manufacturing process, a manufacturer must have the ability to obtain NDC identifiers with minutes of collection 24/7. Most of these products are infused within hours of collection. Recipients are being prepped and irradiated--this would be total body irradiation--while the products are being collected and transported.

Products are generally en route to the consignee before all the data that would be required to obtain the NDC number from FDA is even available--this is where Pat alluded to the specific product counts--if a part of listing and obtaining an NDC number is the amount of active and/or inactive ingredient.

Currently this data is often faxed to arrive at the site of infusion or transplantation by the time the product arrives. The integrity of the product may be compromised if delayed due to a delay in obtaining an NDC number. This could result in a less safe and efficacious product being available for the patient.

The products do have variable contents as opposed to a drug that would have a specified concentration of the active and inactive ingredients. Thus, each HPC or TC would be a law unto itself and would require that the manufacturer obtain different NDC numbers for each.

As stated above, the contents of each of these unique products that must be available in

order to obtain the NDC number is most often not available before the product must be transported to the consignee.

HPCs and TCs are unique products. They are not mass-produced in lots like other drugs. Indeed, it is much more likely that each product is collected for and tailored to a particular patient's needs. Transcription and dispensing errors are very unlikely to occur due to the small amount of product that is given and the limited number of patients that would be receiving the treatment.

HPCs and TCs are not similar to other drugs covered by the NDC requirements of this proposed rule or the rule on barcodes. In fact, some of the comments from the compounding pharmacies and the allergenic products this morning, I think we have some of the same issues.

Our products do not fit the NDC system, we believe, or the other databases that are described throughout the proposed rule. The process of having to obtain an NDC for each product and

potentially each processing step would impose an undue burden on the manufacturer with no positive impact on patient safety.

DailyMed searches were alluded to in the proposed rule. DailyMed searches could not be performed by a patient or patient advocate using the NDC number because the patient and/or physician would not have the NDC number until immediately prior to the infusion. There would be no existing database of information for the product that could be searched and thus no improvement to patient safety by better access to medication information through the DailyMed initiative.

I selected this one because we are really not familiar with the databases. But this is one that I could at least understand.

In general, cellular-therapy products will have been infused before the NDC number is populated in any federally maintained database. Adverse reactions that occur with the patient after infusion are already required to be reported to FDA via the MedWatch form FDA 3500A. This form

recognizes the use of a unique number for product identification and does not require use of the NDC number.

Like some of the other speakers this morning, currently, these products, while they are not licensed, they are actively being used to transfuse and infuse worldwide and we don't participate in anything called the structured product labeling. So that would be a whole other system that we would have to become a part of.

The ISBT 128 standard, as Pat said, is international information. It provides a globally unique product identifier that provides greater benefits in patient safety than does an NDC. Currently, all major standard-setting organizations for cellular therapy have committed themselves to the use of the ISBT 128 as an industry standard.

I won't go over again the group that Pat described other than to say that, in the field of blood transfusion and transplantation, this ISBT 128 is being successfully used worldwide.

The use of the ISBT 128 would ensure that

all imported and exported products using this system could be read by the current computer systems. This we think is critical to the position that we are taking that this would require us to maintain a duplicative system that the NDC could never replace the ISBT 128 because the NDC is meaningless worldwide. For an establishment to send a product in, they, of course, have to register and apparently have to become a part of this system in the proposed rule but products going out, the NDC number is meaningless.

Facilities that manufacture and infuse HPCs and TCs are very familiar with ISBT 128 because it is the labeling system used in hospital laboratories and transfusion services as well as cellular-therapy processing laboratories. These laboratories do not use the NDC codes out on the hospital floor. Perhaps those systems use NDC codes because they get their products from the pharmacy.

The original manufacturer's information which is extremely vital not to be lost in this

trail will never be lost due to relabeling in the NDC system. It is the lower left-hand corner of this labeling patch--it is the lower level; it is either left or right--for all the processing that occurs will be reflected there but the original collector of the product or the original registry that it was collected through would never be lost and it is extremely important that that always be available to everyone handling the products.

The NDC system requires the product to have a new facility or product code assigned as it moves through collecting, processing and distribution systems. The ISBT labeling system does not require recoding. It will decrease transcription error rates and increase trackability of the product.

In addition, in the ISBT system, the product code which must be changed as the product is further processed, is not tied to the manufacturer I.D. and can thus be changed without disturbing the trackability of the product.

ISBT 128 labeling system contains more

information than NDC and can therefore afford a better tracking and tracing mechanism of this product and facilitate quicker recalls. We are talking about recalls from someone in the manufacturer stream, not an FDA recall. These products go quickly.

When a problem is discovered post-infusion, that is likely within days or the first couple of weeks. It is up to the people in the manufacturing stream to put out an alert to the recipient to that physician, not the FDA. That happens months later, weeks, months, later, if that ever happens.

This will also facilitate improvements in deviation management, the ISBT language standard, reporting of adverse effects and outcome follow up.

Again, Pat outlined some of what the ISBT label provides for us and I won't do that again although to say that it goes beyond what NDC would provide and that it is globally unique and it will allow us to capture additional attributes of cellular products.

There is a negative impact of implementing NDC system on these products. Current cellular therapy processing and hospital laboratory computer systems are not designed to accommodate the reading and incorporation of NDC information. New computer systems will be needed by manufacturers and hospitals. Minimally, the current systems will require major upgrades. It is hard to say at this point exactly what the gaps are as the system explained in the proposed rule is not operational.

While pharmacy computer systems may accommodate NDCs, cellular-therapy processing and hospital laboratory systems are unlikely to do so.

Due to the small package size of some products, the NDC label would have to be attached to the product, not adhered to the product. Loss of standardization will occur due to similar products varying only by minor differences in cell counts or in active ingredients having different product codes, even when manufactured by the same organization.

There may be a need to include an

identifier to show multiple products from the same donation. NDC cannot accommodate the various attributes of cellular products. Once again, ISBT 128 has given consideration to the very unique nature of the product and is addressing these requirements.

The requirement to implement NDCs is a de facto requirement to maintain duplicate system for HPCs and TCs. The ISBT 128 labels are central to the success of importing and exporting cellular-therapy products. NDCs do not contain the information necessary to document and track the collection, the processing, distribution and infusion of these products.

Maintaining these duplicative systems is overly burdensome and adds nothing to patient safety. It will result in resources being directed away from processes and initiatives that can add to patient safety. NDC makes no provision for encoding of the donor registry, as Pat alluded to.

The NMDP currently adheres to the confidentiality provisions of the C.W. Bill Young Cell

Transplantation Program to protect the identity of donor centers and apheresis-collection sites.

I think you all know that that happened much later in the subsequent year if donors and recipients are to meet each other. It is confidential up to that point.

FDA is proposing use of a system that has yet to be developed by the agency. However, the cellular-therapy community has been proactive over the last years in assessing the needs for labeling HPC and TC products in a manner to support accurate and complete tracking of the product from the time of collection through various manufacturing processes, during storage and transport to the consignee and ultimately to patient infusion.

The ISBT standard was voluntarily selected for use by the cellular-therapy community prior to these proposals made by FDA. The community has invested much time and money in developing the system as well as implementation plans.

A careful review of the facts indicates that the use of the NDC numbering system, in

addition to the already existing ISBT 128 system, does not offer any increase to patient safety. In fact, we would argue, the implementing of NDC codes for HPCs and TCs will hinder the progress of implementing the superior ISBT 128 information standard for these products.

To require these products to also be labeled with NDCs would force manufacturers to redirect what are very limited resources in order to implement the new manufacturing process that offers no benefit to patient safety. Again, we believe it would be overly burdensome.

NDC will not replace the need to use ISBT 128 and the requirement to track using two different labeling systems will ultimately have a negative impact on patient safety and will open the manufacturing processes to many opportunities for error.

The organizations represented by this statement strongly support initiatives that improve the safety of patients and donors and stand ready to interact with FDA as necessary.

Today, we ask that FDA carefully consider patient-safety issues when evaluating the position put forth in this statement. We believe that the National Drug Code system is not a viable option for improving the safety of hematopoietic progenitor cells and therapeutic cells and that they should be exempt from the requirements found in 21 CFR Part 201 and 207 for the use of the NDC system.

Thank you.

MR. BERNSTEIN: Thank you. Any follow up?

MS. RICHARDSON: I thought I heard you say that your analysis indicated that manufacturers of these products would need to obtain an NDC number for each individual product. Is that what you were implying?

MS. CARR-GREER: Yes. As we read the language of the proposed rule, a part of obtaining an NDC number and the listing components in order to obtain that number is to give the--I don't have a paper to quote, but it is the amount of active and/or inactive ingredient. We don't know that

amount until the product is collected and is in the laboratory being processed.

MS. RICHARDSON: So that is the determining factor in how you came to that conclusion that a new NDC number would be necessary for every individual product manufactured by every individual manufacturer of these products.

MS. CARR-GREER: Yes. Following the language in the proposed rule, that is how--we can't seem to make it mean anything else. The other issues for us are, of course, just entering into a system that is going to be very costly in addition to the systems that are already in use. That is not a small thing.

MS. RICHARDSON: These products would also have lot numbers?

MS. CARR-GREER: No; they do not.

MS. RICHARDSON: They have a unique identifier.

MS. CARR-GREER: They have a unique identifier just like the blood product.

MS. RICHARDSON: Thank you.

MR. BERNSTEIN: Any other follow up?

Thank you. I would thank all the speakers particularly for keeping with the time limits. We pretty much stayed on time.

At this point, I am going to open it up for audience discussion again as we did this morning. If anybody has any comments, feel free to take the floor.

Open Discussion

MR. NEWMAN: Rick Newman. Just two questions. One is, for the information that is going to be submitted to the dockets, do we have any idea how soon after comments are submitted to the dockets they might be available on the web?

MR. BERNSTEIN: I don't know. It varies. I am not exactly sure. It is Dockets Management Branch, I think.

MR. NEWMAN: I have looked and to date there is nothing that is available since the docket was opened. I just didn't know if that was a priority or timing or may never be available on the web. If you could check it out, that would be

helpful.

The second is we didn't really discuss it but combination drug-device products--I understand devices don't have the NDC number. But if you have a combination product--take a drug-eluting stent. Would it have, on that drug-eluting stent package an NDC number for the drug? I don't think it is addressed in the proposed rule. I just was wondering what the group's thinking is on that.

MR. BERNSTEIN: I am not sure offhand. Does anybody--

DR. GARDNER: I am not sure we can get into specifics like that.

MR. NEWMAN: Just in general. I am just talking combination devices in general. Are you thinking that you would, on a combination device, have an NDC number?

MR. LEVIN: Maybe you could express that as a comment. Do you think that there should be?

MR. NEWMAN: Okay.

MR. LEVIN: I didn't mean to chase you away.

MS. CLARK: Lauren Clark. You may tell me the same thing but I haven't heard any comments about NDCs on blood components. In the barcode ruling, the blood products were exempt from barcode rule because of ISBT 128. However, with the proposed 207 Rule, nothing exempted at all. So we are all left to question what was FDA's intent? Was that an oversight?

As somebody was mentioning over here, the way it is worded is that you may be exempted from the barcode rule but the NDC eye-readable number would be expected to be on the blood-product label and, I am assuming, the blood-bag manufacturer's label.

MS. RICHARDSON: There are what we call conforming amendments in the proposed rule that are discussed. So they would be proposed changes to 607.

MS. CARR-GREER: It does exempt the blood-products, that conforming amendment that she is talking about? I don't know if you can say that, but I can.

MS. MORGAN: My name is Kay Morgan. I work for Gold Standard and I am going to give you some of my past history. I spent six years at First Databank populating their file. During that tenure, I populated the Medispan database as well.

There seems to be a perception that you must have an NDC in order to listed on a drug database and thereby be reimbursed through a third-party payer, use in the pharmacy system or be eligible for Medicaid reimbursement.

Let me assure you that the First Databank, Medispan and Gold Standard files have numbers UPCs and HRIs on that file. It is just most users choose to name the field NDC rather than have the computer flip around saying, NDC, UPC, HRI. So there are number fonts on there that are all flagged as to what they are. But the fact that you don't have an NDC will not preclude reimbursement by a state Medicaid or by any other reimbursing firm.

So I just wanted to make sure everyone understands. You don't have to have an NDC to be

on the database or to be paid for by a payer.

MS. PALLA: Madeline Palla with the Animal Health Institute. First, I just have a quick question. The questions that we submitted to the panel previously in writing, are they going to be addressed today or should I form it as a comment now?

MR. BERNSTEIN: We are going to submit those to the public docket. I am glad you raised that because I was going to announce that and I forgot. But those questions will be submitted to the public docket. If you want to summarize now as comments, you can. We will respond to comments that are submitted to the docket in the final rule.

MS. PALLA: For the most part, the questions that we had were addressed in our comments but we look forward to your response in the federal docket.

There is one additional thing that I did not mention. Under the Animal Drug User Fee Act, we charged product fees based on the drug listing.

It is our understanding that a revision to an NDC

number would cause another product to be charged.

So, if a new NDC number needs to be assigned due to a change in a product's packaging, a change in active ingredient or because the current NDC number did not comply with the regulations as finalized, then, under the current EDUFA fee system, AHI members would be charged twice for the drug listing.

The EDUFA fee requirement applies to approved animal drug products that have been listed or submitted for listing. It is also my understanding that the Prescription Drug User Fee Act does not charge fees in the same nature and we are just interested to know how EDUFA was taken into consideration in the writing of this proposed rule and how that will be handled in the collection of fees not to exceed what the CVM is allowed to collect in a given fiscal year.

MR. BERNSTEIN: Thank you.

MS. PEREZ: I am Lauren Perez from Sandler Travis. I have a question regarding, I guess particularly OTC products that are imported. In

order for a product to be deemed misbranded and not allowed into the country, and there is an NDC number on the labeling that may not belong to the person who exported or shipped the product but maybe to a person behind that person in the supply chain, the repackager or relabeler or maybe the original manufacturer, how is customs going to know it is misbranded?

DR. GARDNER: Like I said, we are not here to answer all these questions but to take comment as to what you think the implications might be of what we are trying to propose. Part of the intent of the proposal is to make sure we have accurate information by an NDC number on every product that then can be used by customs and others to properly evaluate those products.

MS. PEREZ: Thank you.

MS. HORN: Heidi Horn, Perrigo. I know that I have had more than my fair share of microphone time today but I have one last comment.

My comment really relates to the proposed rule and its impact on a very large scope of healthcare

products. We are talking biologics, animal health, prescription drugs, OTC drugs, gasses, with very large scope of supply-chain rules, manufacturers, repackagers, packager, labelers, relabelers, with a very large number of objectives.

FDA listed ten objectives. Then we are also talking about drug billing, insurance, Medicaid reimbursement. So I would strongly encourage FDA to look at the very large scope of healthcare products with large scope of supply-chain rules with large scope of objectives and determine whether one system can effectively manage all that.

Thank you.

MR. BERNSTEIN: Thank you. Any other comments? Questions?

MS. GARCIA: Carol Garcia, Alpharma Animal Health. Really, a housekeeping question. The slides that were presented today, will they be available at some point?

MR. BERNSTEIN: I think everything will be in the public docket, on display in the public

docket. That is my understanding. The transcript of the meeting, the slides that were submitted to us prior to the meeting, should all go into the public docket.

MS. GARCIA: Thank you.

Closing Remarks

MR. BERNSTEIN: It looks like there are no other comments. We really appreciate everybody coming in today and taking the time, preparing the comments. We were interested in what you had to say and we will consider all these comments in devising the final rule.

I, again, appreciate the fact that everybody stuck to the time limits as much as possible and kept us moving along and we have actually ended a little bit early. So thank you all for coming and thank you for submitting your comments.

[Whereupon, at 3:28 p.m., the meeting was adjourned.]

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