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August 9, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Re: **Docket No. 02N-0204**; comments concerning Bar Code Label Requirements for Human Drug Products

Dear Sir/Madam:

Please use the attached comments as the official comments to the docket.

Kindly replace the version sent August 8, 2002 with this August 9, 2002 version.

The assistant at 301-827-6860 advised me I could send the revised comments today along with this cover letter.

Please do not enter either the August 8, 2002 version or this cover letter into the docket.

Regards,

A handwritten signature in cursive script that reads "Jill Jarusiewicz".

Jill Jarusiewicz
Manager, Regulatory Affairs

02N-0204

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Re: **Docket No. 02N-0204**; comments concerning Bar Code Label Requirements for Human Drug Products

Dear Sir/Madam:

Novartis Consumer Health, Inc. appreciates the opportunity to submit comments to Docket No. 02N-0204.

NCHI supports efforts to reduce medication errors, which may ultimately reduce adverse drug events. NCHI advocates the evaluation of barcode addition to outer container labels of retail OTC drugs as an additional tool to aid the professional healthcare community in their safe use of OTC drug products.

NCHI does not believe the unique product identification number should be linked to either the Universal Product Code (UPC) or the National Drug Code (NDC) for OTC drug products.

NCHI respectfully requests the agency consider establishing a separate final rule for OTC drug products. The comments below support the uniqueness of the OTC industry that justifies a regulation separate and distinct from prescription drugs.

NCHI submits the following comments to the Docket after considering the contents of both the 6/18/02 Federal Register Notice and the Public meeting held at NIH on 7/26/02.

Federal Register Questions: Please note – all responses are specific to OTC drugs. NCHI has no comments regarding the application of bar codes to prescription drugs, medical devices or biologics.

A. General Questions Related to Drugs and Biologics:

1. Which medical products should carry a bar code? For OTC drugs, all retail products with specified dosing amounts and regimens should have bar codes on their outer container labels. Certain categories of products, which carry little or no risk for causing ADEs in institutional settings (e.g., lip balms, sunscreens) should not be required to incorporate bar codes into their labeling. Additionally, free consumer/physician samples should be excluded from a bar code requirement. Neither consumers nor office physicians are expected to have bar code scanning

systems. It is not anticipated that barcodes would result in a reduction of ADEs in these groups.

- What information should be contained in the bar code? The bar code should consist of a unique product/label version identification code that is established, updated and maintained by each drug distributor.** The bar code should begin with a distributor's labeler code to ensure no two companies choose identical codes. The remainder of the bar code number should be assigned internally by the distributor. The distributor should be responsible for assuring a unique product code for each product/label.

The bar code should not be linked to the product UPC or NDC code. In the OTC industry, the UPC code does not always link to the NDC code, nor should it. There are times when a change is made to labeling which does not trigger or require a change to the UPC or NDC number. These changes often pertain to information which needs to be reviewed and assessed by health care professionals (i.e., inactive ingredient changes, cation content addition, text changes as per monograph finalization, addition of warning information as per final regulations, etc.). Health professionals need to be aware of these changes. If scannable bar codes are linked to numbers which are constants in many of these circumstances, (UPC/NDC), it is conceivable that important label changes may go unnoticed as health professionals increase reliance on scanned codes. NCHI believes the establishment of a unique code which is selected and updated by the product distributor will help call attention to label changes. A product distributor will be able to revise these scannable codes when a label change is made. Therefore when a revised label is scanned into an institution's system, it will not match the "old" code and will require the dispenser to read the label and update their systems accordingly.

UPC Related Comments

There are negative implications for industry should the agency require the scannable code to be the UPC number. The UPC number is the lifeline of each retail shelf keeping unit (SKU). The UPC code system works as an effective tool for a variety of reasons as elucidated in the presentations of John J. Roberts and John Terwilliger of the UCC at the 7/26 public hearing. NCHI does not support any regulation that could potentially disrupt the effectiveness of the current system. Additionally, NCHI believes a link to UPC would result in frequent, unnecessary changes to UPC codes.

Each SKU of a product has a unique UPC code – such uniqueness is needed for various inventory and tracking systems currently in use but is not necessary for a bar code system designed to reduce medication errors. It appears the intended purpose of bar coding is not to identify whether a consumer receives product from a blister pack, bottle of 30's, 50's or 100's. Rather, the critical element is identification of the product they receive. Establishment of a unique code by distributors would allow one number to be created per product as opposed to per SKU. Such a system would be easier to maintain from both a manufacturer and healthcare provider perspective, as it would reduce the number of codes to be maintained in the overall system while still providing the critical information desired by healthcare professionals in institutional settings.

NCHI Sales force representatives have communicated that retail outlets discourage changes to UPC codes. Such changes have spiderweb implications as they affect every level of computer/inventory management systems. These systems

identify each product SKU by its UPC and most do not have the ability to link multiple UPCs to a single SKU. Changes to UPCs result in manual labor expenditures, which are backcharged to distributors as "slotting fees". "Slotting fees" are charged when distributors "sell in" a new SKU or change UPCs on existing products. These fees vary greatly depending on retail outlet, distributor, product and situation. Price estimates provided range from \$100,000 to \$500,000 in slotting fees for a single product (this is a total for all outlets). Should the agency require industry to use the UPC code as the scannable bar code, NCHI expects the slotting fees paid on an annual basis to increase tremendously. This expectation is based on the perceived need to change the bar code when any label changes are made. Finally, UPC changes affect not only our customers' systems but they affect NCHI internal systems as well. Internal manpower expenditures would be greatly increased for UPC changes.

NDC Related Comments

There are negative implications should the agency require the scannable code to be the NDC number. For the reasons outlined above, using the NDC code, as the scannable code would translate to many unneeded changes to product NDC codes. The additional workload requirements are not as great as those for UPC codes, but would include increased manpower for NDC code management, change control and drug listing/delisting activities.

What information should be contained in the bar code? What do you consider to be critical bar code information that will reduce medical product errors? What information would be helpful but not necessarily critical for reducing medication errors? **The critical factor for reducing medical product errors is the establishment of a well-managed link to a database maintained by the healthcare institutions according to their needs.** The bar code should be viewed solely as a link or a pointer to this database. The code should be managed by the distributor to allow code revisions, as medically relevant information is added/changed on the product.

3. Considering current scanners and their ability to read certain symbologies, should the rule adopt a specific bar code symbology? Should we adopt one symbology over another, or should we allow for "machine readable" formats? What are the pros and cons of each approach? NCHI does not recommend one specific symbology at this time but encourages the agency to allow maximum flexibility for symbology choice. As OTC industry discussions of the applicability of bar coding to OTC drugs began with the publication of the meeting notice on 6/18/02, NCHI has not had time to investigate the feasibility or cost implications of any particular approach. At this time we are encouraged by the words of the representatives of the UCC at the 7/26 meeting and will focus our efforts on those symbologies, which the UCC favors.
4. Assuming that we require bar codes on all human drug products, where on the package should the bar codes be placed? Are there benefits to placing bar codes on immediate containers, such as the bottles, tubes, foil-wrapped tablets, and capsules found inside prescription or OTC product cartons? Is there a way to distinguish whether certain containers with a bar code will have a more significant effect on preventing errors than others? For OTC drug products, NCHI believes the bar codes should be placed on a panel of the outer retail package. FDA should not require bar codes on the immediate use container unless it is not sold with an outer retail package (similar to Drug Facts Regulations). As the agency is aware, the main purpose of the OTC label is to provide information to consumers in a self-care setting for safe and

effective product use. Often these labels do not allow for additions of text to the package. The largest amount of label space is available on the outer retail package. Inner packages often contain small tubes, bottles, blisters, etc. where industry struggles to fit important consumer information in the largest possible type size for consumers. Adding bar codes to these already crowded labels would not aid and would in fact cause further impediments for consumer comprehension of these labels. This statement is based on label comprehension studies performed by the agency that led to minimum type size requirements for Drug Facts labeling. It was shown that type size is a critical element in consumer comprehension. At this time, consumers do not have the ability to scan bar codes nor do they have access to a database to make the embedded information useful.

Further, NCHI does not believe the code should be mandated on the information panel. Instead, industry should be given the flexibility to put the code on whichever panel can best accommodate it. The information panel space is currently used for important "Drug Facts" information that should not be compromised for a bar code.

From the video presented by Kay Willis, Chief of Pharmacy SPD Veterans Administration Medical Center North Chicago at the 7/26/02 public meeting, the understanding is that healthcare professionals can scan the product once and generate their own labels. These labels can be placed on each unit that is repacked or dispensed. Based on this approach there do not appear to be patient benefits by requiring the code on the inner container when an outer package exists.

5. What products already contain bar codes? Who (i.e., hospitals, nursing homes, outpatient clinics, retail pharmacies, etc.) uses these bar codes and how? Each retail SKU sold by NCHI contains a bar code (the UPC number). For the reason stated above we do not suggest using this number. Some products contain additional bar codes that are used for label verification purposes.

B. Medical Device Questions: NCHI has no comments on Section B at this time.

C. General Questions and Economic Impact Questions

1. Will bar code printing costs cause you to modify your packaging choices, such as reconsidering the use of blister packages or influencing future package choices? If so, how? NCHI has not yet conducted an internal economic impact analysis. NCHI does not currently market any packages in the retail setting that consists solely of blister packages. All blister packages sold at retail are sold within an outer package such as a carton. As stated below NCHI does not support bar coding down to the unit of use (i.e., blister unit). Our current blister packages contain important information for the consumer including some or all of the following: product name, ingredient/quantity information, dosing information, package opening instructions, storage statements, lot number, exp. date, company signature. NCHI labels blisters with as much consumer information as practicable. NCHI does not support eliminating information that contributes to the safe and effective use of our OTC products in the self-care environment.

2. Have you implemented bar code technology in your product line? If so, what elements and symbology are included in the bar code? NCHI does not currently print bar codes on line. The bar codes that currently appear on our labeling are pre-printed along with the other standard label information. We support the code system proposed above which

would allow the new bar code to be either pre-printed or printed on line. This choice would give distributors maximum flexibility in implementing the bar codes. Pre-printing could potentially reduce both the capital expenditures and time needed to design, order, validate and implement a new on-line printing system

3. *If you manufacture and bar code products, how do verification requirements for bar codes affect your ability to add bar codes? How much barcode verification is appropriate as party of the quality system?* NCHI has no comments at this time.

5. *Can bar codes be produced with a dose specific unique identifying number, lot number, and expiration date at your highest production line speeds?* A feasibility analysis has not been performed at NCHI. However we support a system that allows a unique product identifying number to be pre-printed or printed on-line. NCHI does not agree with the inclusion of the lot number or expiration date in the bar code at this time. Each unit of product distributed by NCHI is clearly marked with a lot number and expiration date that could be inputted and utilized by the institution's system if they deem appropriate for tracking. After listening to the discussions presented at NIH, it appears that lot/exp. is not a critical element expected to result in reduced medication dispensing errors. A reduction in medication errors is in fact the goal of this regulation. NCHI supports activities that could result in cost savings to the healthcare system but does not believe such regulations should be implemented without a complete economic analysis for all parties involved. To our knowledge such an analysis has not yet been performed.

6. *What equipment solutions are vendors offering to manufacturers for bar coding or scanning? How quickly can such systems run? What type of packaging line is equipment used for?* NCHI has no input on this series of questions.

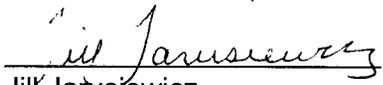
7. *What is the expected rate of technology acceptance in all health care sectors of machine-readable technologies? What are the major inhibiting factors to the current use of machine readable technologies? What would be the expected benefit of using machine readable technology in the delivery of health care services (including drug products)? What would be the expected benefit of machine readable technology for other potential uses (e.g., reports, recordkeeping, inventory control, formulary setting, etc.)?* NCHI has no input on this series of questions.

8. *Assuming a final rule is issued requiring bar coding, when should it become effective? For example, would some industries or products require more time than others to comply with a bar coding requirement? Would a certain compliance time sharply reduce costs of relabeling?* This rule has implications for each SKU of product covered. The time needed for effective implementation is a variable that is dependent on the scope and requirements of the final rule. The responses to the previous questions outline some of the variables that will affect the time needed for implementation. Since it appears the scope will be similar to that of the Drug Facts final rule, a similar period for implementation is recommended. Whether bar codes are pre-printed or printed on line, all affected labeling will require reformatting to facilitate placement of the bar code. A three (3) year compliance time will sharply reduce the costs associated with the art revision aspect of the process as it will enable companies to phase in the bar code label format with other ongoing artwork revisions.

In closing, NCHI supports the evaluation of barcode addition to outer container labels of retail OTC drugs as an additional tool to aid the professional healthcare community in their safe use of OTC drug products. It appears the most efficient and effective

means of meeting the needs of all stakeholders in the process would be issuance of a final rule specific to OTC drugs which accounts for the market forces and regulations specific to these products whose primary use is in the self-care setting.

Respectfully submitted,
Novartis Consumer Health, Inc.,


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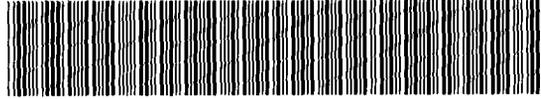


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