Boehringer Ingelheim
Roxane Laboratories

January 5, 2007

Division of Dockets management (HFA-305)
Food and Drug Administration
5630 Fisher Lane Rm 1061
Rockville, MD 20852

RE: Docket No. 2005N-0403 and RIN 0910-AA49

To whom it may concern:

Roxane Laboratories, Inc. would like to thank The Food and Drug Administration for the chance to comment on the proposed rule for Docket No. 2005N-0403 (RIN 0910-AA49) "Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated under a Biologics License Application, and Animal Drugs".

As a member of the Generic Pharmaceutical Association (GPhA) we would like to express our agreement with the comments they submitted on November 24, 2006 (see attached copy).

We would like to focus our concerns on the agency proposal that the NDC number "would be assigned prospectively by us to drugs that have not previously been assigned NDC numbers by a manufacturer, repacker, or relabeler."

Our current process for assigning NDC numbers (see DP M-DRA204/02) is that a number is requested, usually 18-24 months prior to ANDA submission, and then within five business days the number is to be assigned in a database and provided to the requestor. Although we have five days to assign the number it is usually done within minutes of the request. If we were to request this information from the FDA we would (1) have to work further in advance and (2) work with an uncertainty of when we might receive the number. The latter of these could have a domino effect on other deliverables that are generated using the NDC number.

In the generic drug industry it is not uncommon to add SKU's at the last minute before filing the ANDA. Would we have to delay filing these additional SKU's until the agency assigns new NDC numbers? This could result in the filing of additional amendments, thus taking more time to review and receive approval.

As the process is currently, we sometimes need to change the NDC number if we make changes to our formulations (i.e. inactive ingredients) there have been several cases which this has occurred. The evaluation on whether or not to change an NDC number is dependent on if the change causes the product to visible different. With the current

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proposal outlined we are concerned that we and other companies would unnecessarily have to change NDC numbers which does not add value and only additional work for both Industry and the FDA. In addition there is only a finite number of numbers that can be used by companies in the current system so using numbers for insignificant changes would be silly. (During the Public Meeting held on December 11, 2006 it was mentioned several times that a new labeler code could be issued if a company ran out of product codes. This seems like a quick fix to the potential problem. Do multiple labeler codes for each company defeat the purpose of the labeler code?

Similar to the change in inactive ingredients, we would like to keep the NDC number if there is a change in API suppliers. These numbers are linked to the way our customers order/reorder our products. A new NDC number could cause confusion with our customers who simply want the product and are not concerned with who we purchase the active ingredient from. Roxane Laboratories already has product manufactured using two different suppliers of the active on the market. They are approved in the application. Studies are done to show that using different API's do not change the safety and/or efficacy of the product so what value would it be to assign NDC numbers to the same product just because the API is different? We believe that having two NDC numbers for the same product would only cause confusion for us, the FDA and most importantly our customers.

Another concern we have is the cost of labeling changes every time the NDC number changes. The amount of time it takes to change the bottle labels and leaflet, submit the artwork for approval, submit the changes to the print vendor, the cost of the new labeling, destroy existing labels, and QC it all is an extraordinary undertaking by both FDA and industry. This will certainly generate much more paperwork than the current process. Additionally, the risk for errors increases exponentially.

As a player in the generic drug industry we are highly sensitive to the fact that timing and confidentiality are keys to the success of our products. What processes will be in place to ensure that the NDC information is kept strictly confidential until the time of approval? If the brand company or another generic competitor got a hold of this information it could give them a significant advantage in the marketplace.

As stated previously, our current process is to use a database to track all of our NDC numbers. When assigning a new NDC number, the database shows only those numbers that have NOT been used (in sequential order). Once a number is assigned to a product it is moved to a separate part of the database that lists (alphabetically or numerically) all NDC numbers and their respective products. How will the FDA be able to track this information for each individual company? Doesn't it make more sense to train companies to create and maintain this information on their own? Isn't it the company's responsibility to adequately maintain NDC listings?

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Roxane Laboratories, Inc. would like to suggest that FDA set up a working group with industry members (including members of the human drugs, animal health, compressed gas, and repackaging communities). This would give the agency a chance to get more in-depth detail on how each of these companies work and how the proposed rule would affect their individual processes. We would be more than happy to participate in any efforts to make this process as robust as possible.

If you have any additional questions or comments, please feel free to contact Elizabeth Ernst at (614) 272-4785.

Again, we thank you for this opportunity to express our thoughts and concerns.

Sincerely,

Elizabeth Ernst
Associate Director, for Drug Regulatory and MedicalAffairs, Multisource
Roxane Laboratories Inc.