GE Healthcare

101 Carnegie Center
Princeton, New Jersey 08540
USA

November 16, 2006

Division of Documents Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 2005N-0403
Comments to Proposed Rule on Establishment Registration and Listing

Dear Documents Management Staff:

Reference is made to the subject docket number published in the Federal Register Volume 71, Number 167, page 51276 which announced proposed rule on the "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."

At this time, as requested by the Federal Register notice, GE Healthcare is providing questions and comments to the proposed rule on the following pages.

This submission is made in duplicate. Please call me at (609)-514-6573 if you have any questions or comments regarding this submission.

Sincerely,
GE Healthcare

Fred Longenecker
Director, Regulatory Development

2005N-0403

C 4

Proposed Rule on Establishment Registration and Listing

(Docket No. 2005N-0403)

GE Healthcare Comments

(1) Moving towards an electronic system will provide efficiency; however, we request that the Agency provide clarity regarding how the proposed Establishment Registration and Drug Listing system is intended to interface with the Structured Printed Labeling – Physicians Labeling Rule (SPL-PLR) systems recently instituted by the Agency. There appears to be duplication of drug listing information within these two systems.

(2) There were discussions earlier this year regarding the Data Element (Codes) Descriptions and Meta-Data content that would replace the existing Drug Listing system. We request clarification regarding how the Data Element (Codes) Descriptions and Meta-Data content will fit into the newly proposed drug listing process.

(3) We question whether it is necessary under the proposed Establishment Registration and Drug Listing electronic system to submit product labeling as part of the drug listing process when the recently instituted SPL-PLR system will provide this more completely. We think this may be unnecessary duplication of effort.

(4) Under the proposed Establishment Registration and Drug Listing electronic system, it states that FDA may assign the NDC number upon receipt of a request including specific information from the sponsor. Please clarify the expected timeframes for assignment of this NDC number so the process does not result in unnecessary delay to sponsors.

(5) Please clarify the means (e.g., phone, mail, e-notification) by which an NDC number assignment by the Agency will be communicated to the sponsor.

(6) The proposed rule states that the "preferred" NDC number used on product labeling would contain the labeler code of the last manufacturing site for the drug immediately before the product is received by the wholesaler or retailer. When the proposed rule becomes effective if this "preference" becomes a requirement (rather than a preference), it would be burdensome for sponsors who employ a common NDC number (containing the distributor labeler code) for products with that are manufactured at multiple international manufacturing sites. Such a requirement would create an excessive time and cost burden for sponsors to track and change individual manufacturing NDC numbers for product from individual manufacturing sites. GE Healthcare requests that this part of the proposed rule remain a preference rather than become a requirement.

(7) The proposed rule for the Establishment Registration and Drug Listing electronic system states that it would operate via the Internet. In regard to this system we have the following comment and questions.

- Please provide information on the measures proposed to maintain the system with a minimum of "downtime" and provide for an alternate means of accessing necessary information during such periods.
- What plans does the Agency have for technical support for the site?

- Will the proposed electronic system allow Sponsors to save the completed data (ie. Drug Listing and Establishment Registration forms) that is forwarded electronically via the internet to the FDA?
- What plans does the Agency for issuance of a Guidance to Industry for using the proposed electronic system?