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January 23, 2007

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

Subject: Docket # 2005N-0403/RIN 0910-AA49

Dear Sir/Madam:

Pharmion Corporation submits these comments regarding the proposed rule "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 published in the August 29, 2006 Federal Register.

Pharmion Corporation is a global pharmaceutical company that currently markets two human prescription drug products in the US, for which we hold the New Drug Applications. Additional products are under development, and Pharmion will be the "applicant" who submits and owns the NDAs for those products. However, the company does not own, and does not intend in the foreseeable future to acquire, any establishments which perform any steps in the manufacture of our products. Instead, we rely upon contract manufacturers to manufacture, test, package, and label our products in compliance with our NDAs. Pharmion currently uses its own labeler code on the labeling of its marketed products, and submits drug listing information for its products. Pharmion is therefore not a "manufacturer," "repacker," or "relabeler" as defined under proposed 21 CFR 207.1, and would be considered a "private label distributor." It is from that perspective that we submit our comments on this proposed rule.

Proposed 207.33(a) would require FDA to assign all sections of the NDC number, rather than allowing the manufacturer or distributor to assign the product and package code. Pharmion believes that manufacturers, repackers, relabelers, and private label distributors should be allowed to continue to assign the product and package codes. Many companies use a system for assigning NDC numbers that includes some meaning in the assigned number. This meaning would be lost if FDA were to assign numbers randomly.

Proposed 207.33(b)(3) states that the manufacturer, repacker, or relabeler who processes the drug for a private label distributor is responsible for obtaining the NDC number from FDA.

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- The Federal Register notice states that this change “ensures that more accurate information is provided to FDA about the drug distributed by the private label distributor because the manufacturer supplies the necessary drug information” (manufacturer information, drug’s names, active and inactive ingredients [or application number], dosage form, package size/type, marketing status, type of drug, imprinting information, distributor information, and proprietary name assigned by the distributor) to FDA.

If NDC numbers are to be assigned by FDA, then Pharmion believes that a private label distributor who is an applicant (who owns the NDA) should be the party who obtains the number from FDA:

- The applicant is equally capable of providing accurate information as the contract manufacturer.
  - If NDC numbers must be requested by the manufacturer, then a single product which is manufactured by more than one manufacturer would have multiple NDC numbers despite being the same product. For example, if the approved NDA provides for more than one contract manufacturer, as is often the case with high volume products or those with produce with capacity constraints, each would be required under the proposed rule to obtain an NDC number. Since the NDC number is used for ordering product, this would cause confusion in the marketplace and require the private label distributor to maintain excess inventory.
- The Federal Register notice states that by requiring manufacturers, repackers, and relabelers to submit information on behalf of private label distributors, the proposal would eliminate the potential for redundant, incomplete, or inconsistent submissions by private label distributors.

Pharmion believes that this goal could also be achieved by requiring only the owners of the approved applications to submit the information necessary to obtain an NDC number.

The Federal Register notice states that if a drug already has an NDC number at the time of the effective date of the final rule, the drug would retain that number provided the manufacturer, repacker, or relabeler reviews and updates the information in FDA’s database within 9 months after the effective date of the final rule. If this is not done, FDA may assign a new NDC number. Again, Pharmion believes that the applicant should be the party who is required to verify the information.

Proposed 207.33(c)(1), (c)(2), (c)(3), (d)(1) and (d)(2) would require manufacturers and repackers to provide information about package size and type. The Federal Register notice provides an example (a drug packaged in a box containing a card of 12 unit-of-use blisters) and states that distinct NDC numbers for each “package level” would enhance the bar code’s accuracy and value. Pharmion believes that the proposed rule is unclear regarding what “package levels” will require different NDC numbers. To take FDA’s example further, if there were a unit-of-use blister, a card of 12 blisters, a carton

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containing 1 card of 12 blisters, a carton containing 2 cards of 12 blisters, and a shipper containing 10 cartons, which of these "package levels" would and would not require a distinct NDC number? As another example, if a vial was sold only in a carton containing a single vial, would the carton and vial have distinct NDC numbers? Pharmion therefore requests that FDA clarify the requirement regarding distinct NDC numbers for each "package level."

Under proposed 21 CFR 207.41(c), private label distributors would not be permitted to register or list. As stated in the August 29 Federal Register notice, "under section 301(p) of the act, it is a prohibited act to fail to submit drug listing information under section 510(j) of the act. Failure to submit drug listing information would also render a drug misbranded under section 502(o) of the act." Pharmion Corporation strongly believes that we as the owner of the NDA should be allowed to list our products. We have a vested interest in assuring that our products are in compliance with the act and regulations.

FDA specifically requested comments on whether FDA should require manufacturers, repackers, relabelers, and drug product salvagers to provide the number of batches and batch size for each drug subject to the drug listing requirements. FDA is considering this requirement because it would provide important data regarding a product's volume in the US marketplace to assess the potential impact the product has on the public health. Pharmion believes that this requirement is unnecessary. The amount of drug distributed each year is already required to be provided in the NDA annual report; see 21 CFR 314.81(b)(2)(ii). Distribution reports are required for biologics every 6 months; see 21 CFR 600.81.

Pharmion agrees that electronic submission of registration and listing information would increase the efficiency of the registration and listing process, and supports FDA's efforts to create and implement such a system.

We appreciate your consideration of these comments.

Sincerely,



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Senior Director, Regulatory Affairs  
Pharmion Corporation

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