National Home Infusion Association
Providing solutions for the infusion therapy community

March 4, 2014

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: "Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act; Request for Nominations"

Docket Number: FDA–2013-N-1523

Dear Commissioner Hamburg:

The National Home Infusion Association (NHIA) submits these comments on the draft guidance made available on December 4, 2013 by the Food and Drug Administration (FDA) entitled "Drug Products That Present Demonstrable Difficulties for Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act; Request for Nominations." NHIA is a national membership association for clinicians, managers and organizations providing infusion therapy services for patients in the home and other outpatient settings.

NHIA understands that FDA is obligated by Section 503A and 503B to develop a list of drug products that present demonstrable difficulties for compounding. NHIA recommends that in carrying out these obligations the FDA utilize a transparent and open process that provides stakeholders with meaningful opportunity to comment on the drugs that the FDA proposes to include on the list. Thus, NHIA recommends that the FDA utilize a formal notice and comment period not only for establishing this list, but also for updating it.

In addition, we believe that the FDA should conduct public meetings related to the list for interested stakeholders to discuss which drug products should initially be included on the lists. FDA also should meet with provider groups and trade associations to discuss the drug products being considered for the list. We believe that soliciting feedback through various channels is important to ensure that the FDA obtains the most helpful and current advice about the appropriate drug products to be included on the list. After the FDA receives feedback through these means, NHIA recommends that the FDA

issue the list in proposed form so that stakeholders have the opportunity to comment on the drug products included therein.

In addition, the FDA should ensure there is an open and ongoing process that provides stakeholders with meaningful opportunities to petition for the removal of a product from the demonstrably difficult to compound list. The FDA may consider establishing a regular schedule under which the Agency requests feedback on the list. This predictable and transparent process will encourage stakeholders to continuously invest time in preparing and submitting thoughtful, evidence-based recommendations on the demonstrably difficult to compound list.

Also, due to the unique needs of each individual patient and the lag between scientific developments and regulatory updates, NHIA believes that the FDA should establish a process for physicians and pharmacists to petition to have a drug product on the demonstrably difficult to compound list made available for compounding. Should a drug shortage occur where a drug product is needed, it may become imperative that a process be in place to move swiftly to make the drug product available for compounding.

NHIA is concerned that the FDA issued questions regarding drugs to be nominated for the demonstrably difficult to compound list, but did not specify the criteria that it intends to use to determine the drugs that will be placed on the demonstrably difficult to compound list. This underscores the need for the FDA, when it publishes the list and seeks comments from the public, to explain in meaningful terms the reasons why each drug was included in the list. The demonstrably difficult to compound list will effectively ban compounding of certain drug products and the FDA needs to ensure that the list does not lead to patient harm by preventing access to a needed drug. We would hope that such issues as availability of alternative drug products and drug shortages should be considered when deciding whether a drug should be placed on the list.

Please feel free to have your staff contact Kendall Van Pool, NHIA Vice President of Legislative Affairs, at (703) 838-2664 or kendallvanpool@nhia.org should you want to discuss our comments further. Thank you for your consideration of NHIA's views.

Sincerely,

Russell Bodoff
President & CEO
National Home Infusion Association