

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0404]

Novel Formulations of Dialysis Solutions; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to gain input from interested persons on how solutions used in hemodialysis or peritoneal dialysis should be evaluated for safety and efficacy. More specifically, the agency is interested in collecting comments on the development of formulations containing novel concentrations of electrolytes and simple sugars, but no new molecular entities.

DATES: The public meeting will be held on September 27, 2004, from 9 a.m. to 4 p.m. Written or electronic comments on dialysis solutions are welcome at any time.

ADDRESSES: The public meeting will be held at the Doubletree Hotel, 1750 Rockville Pike, Rockville, MD. Public parking is available at the hotel. The Doubletree Hotel is also accessible by Metro at the Twinbrook Station on the Red Line.

Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT: Norman Stockbridge, Center for Drug Evaluation and Research (HFD-110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5365, e-mail: *Norman.Stockbridge@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is holding a public meeting to discuss the nature of development programs for solutions used in hemodialysis or peritoneal dialysis. The discussion will be limited to solutions containing only simple sugars and the electrolytes and other small molecules normally found in plasma. Solutions containing novel oncotic or osmotic agents more clearly resemble conventional drugs and are subject to conventional drug development programs, with the usual characterization of safety and effectiveness through clinical studies. The discussion will focus on the following questions:

- For solutions with no novel constituents, what clinical studies are necessary?
- Are there acceptable ranges of individual sugars and electrolytes that can be established in clinical studies so that a novel product would not need to demonstrate its ability to act as a dialysate?
- Are there additional constraints for combinations of ingredients, for example, to constrain the overall osmolarity?
- In the absence of clinical studies to show safety and effectiveness, how would appropriate instructions for use be established?

If you need special accommodations due to a disability, please contact Norman Stockbridge at least 7 days in advance.

II. Comments and Transcripts

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on dialysates. Two paper copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number

found in brackets in the heading of this document. Comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

There will be no transcript of this meeting.

Dated: September 9, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S