1997. Space is limited, therefore, interested parties are encouraged to register early.

If you need special accommodations due to a disability, please contact R. Thomas Trout at least 7 days in advance.

Dated: August 26, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–23243 Filed 8–27–97; 3:24 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0228]

Draft Guidance for Industry on Computerized Systems Used in Clinical Trials; Availability; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period on the draft guidance entitled ''Guidance for Industry: Computerized Systems Used in Clinical Trials'' until November 3, 1997. FDA published a notice of availability of the draft guidance in the **Federal Register** of June 18, 1997 (62 FR 33094). FDA is reopening the comment period in response to requests for additional time to review the agency's draft guidance on the use of computerized systems in clinical trials.

DATES: Written comments may be submitted on the draft guidance document by November 3, 1997. General comments on agency guidance documents are welcomed at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: James F. McCormack, Office of Enforcement (HFC–230), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0425.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 18, 1997, FDA announced the availability of a draft guidance for industry entitled ''Guidance for Industry: Computerized Systems Used in Clinical Trials.'' The draft guidance is intended to assist applicants who wish to use computer systems to generate, collect, maintain and transmit clinical data for submission to FDA in support of marketing or research applications. The notice invited interested persons to submit written comments on the draft guidance by August 18, 1997.

The agency received a number of requests for additional time to comment on the draft guidance and is reopening the comment period until November 3, 1997.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 25, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–23180 Filed 8–29–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0333]

Reexamination of the Evaluation Process for Liquid Chemical Sterilants and High Level Disinfectants; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a position paper entitled ''Reexamination of the Evaluation Process for Liquid Chemical Sterilants and High Level Disinfectants.'' The position paper is soliciting input from industry, users' groups, other regulatory agencies, and academia on FDA's approaches to improving the evaluation of liquid chemical sterilants and high level disinfectants.

DATES: Written comments by December 1, 1997.

ADDRESSES: Submit written requests for single copies of the position paper to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6597 (toll free outside of MD 1–800–638–2041). Send two self-addressed adhesive labels to assist that office in processing your requests. Submit written comments on the position paper to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. A copy of the position paper and received comments are available for public examination in the Docket Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–0616.

SUPPLEMENTARY INFORMATION: FDA regulates the introduction of medical devices into interstate commerce. A person intending to market a liquid chemical germicide medical device must submit a premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)) to FDA before introducing the device into interstate commerce. Regulations governing the general content and format of 510(k) submissions (part 807 (21 CFR part 807)) and other regulatory requirements are discussed in guidance documents available from the Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (address above). The effective use of chemical germicides is important in preventing nosocomial infections. Comprehensive, scientifically sound criteria for the evaluation of chemical germicides is essential to help ensure that these agents are safe and effective for their intended use when used according to their labeling. FDA recognizes the importance of providing applicants, and other interested parties, with the agency's evaluation criteria for chemical germicides in order to facilitate the assembly of necessary data, to maintain consistency of review, and to provide for a more efficient regulatory process. The purpose of this position paper is to solicit input from industry, users' groups, other regulatory agencies, and academia on FDA's approaches to improving the evaluation of liquid chemical germicides. The comments that FDA receives in response to this position paper will help it in assessing the current guidance and in developing the approach that will be used in future guidances for these products.