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Draft Guidance for Industry on Computerized Systems Used in Clinical Trials; Availability; Reopening of Comment Period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SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period on the draft guidance entitled ''Guidance for Industry: Computerized Systems Used in Clinical Trials'' until November 3, 1997. FDA published a notice of availability of the draft guidance in the **Federal Register** of June 18, 1997 (62 FR 33094). FDA is reopening the comment period in response to requests for additional time to review the agency's draft guidance on the use of computerized systems in clinical trials.

DATES: Written comments may be submitted on the draft guidance document by November 3, 1997.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SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 18, 1997, FDA announced the availability of a draft guidance for industry entitled ''Guidance for Industry: Computerized Systems Used in Clinical Trials.'' The draft guidance is intended to assist applicants who wish to use computer systems to generate, collect, maintain and transmit clinical data for submission to FDA in support of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 The notice invited interested persons to submit written comments on the draft guidance by August 18, 1997.

The agency received a number of requests for additional time to comment on the draft guidance and is reopening the comment period until November 3, 1997.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above).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.

This position paper represents the agency's current thinking on the Reexamination of the Evaluation Process for Liquid Chemical Sterilants and High Level Disinfectants. It does not create or confer any rights for or on any persons and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons should submit to the Dockets Management Branch (address above) written comments on the ''Reexamination of the Evaluation Process for Liquid Chemical Sterilants and High Level Disinfectants'' by December 1, 1997. 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. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Persons interested in obtaining a copy of the position paper may do so by using the World Wide Web (WWW). The Center for Devices and Radiological Health (CDRH) maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a PC with access to the Web. Copies of the position paper can be accessed from the CDRH home page at ''http://www.fda.gov/cdrh.''

Dated: August 18, 1997.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 97–23181 Filed 8-29-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–0525.

Treatment Outcome Performance Pilot Studies (TOPPS)

—New—SAMHSA has awarded contracts to 14 States to develop and pilot test performance and outcomes measures for substance abuse treatment services. The pilot studies will collect data from substance abuse clients, including pregnant women, women with dependent children, adolescents, and managed care clients. Measures of addiction severity and other outcomes will be obtained at admission, discharge, and post-discharge. The estimated annualized burden for the two-year project is summarized below.

No. of respondents	No. of responses/ respondent	Average burden/ response	Total burden hours
6,419	2.0	0.51	6,551

Written comments and recommendations concerning this information collection should be sent within 30 days of this notice to: Dan Chenok, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: August 19, 1997.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 97–23174 Filed 8–29–97; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4263–N–12]

Notice of Proposed Information Collection for Public Comment

AGENCY: Office of the Assistant Secretary for Housing, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due: November 3, 1997.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Oliver Walker, Housing, Department of Housing & Urban Development, 451—7th Street, SW, Room 9116, Washington, DC 20410.

FOR FURTHER INFORMATION CONTACT: Georgia Yeck, telephone number (202) 708–2866 (this is not a toll-free number) for copies of the proposed forms and other available documents.

SUPPLEMENTARY INFORMATION: The Department will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended).

The Notice is soliciting comments from members of the public and affecting agencies concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

This Notice also lists the following information:

Title of Proposal: Supplement to Subscription Agreement for Cooperative Housing Applicants under Section 213 and 221(d)(3).

OMB Control Number: 2502–0058.

Description of the need for the information and proposed use:

This proposed information collection is required under section 213 and 221(d)(3) of the National Housing Act authorizing the Secretary to insure mortgages covering property held by a non-profit cooperative ownership housing corporation. To determine the capacity of the borrower corporation and the individual members to meet the statutory requirement for repayment, HUD must review information as to the applicant's financial and credit history.

Form numbers: HUD–93232A.

Members of affected public: Non-profit cooperative housing corporations.

An estimation of the total numbers of hours needed to prepare the information collection is 3.500, the number of respondents is 5,000, frequency of response is 1, and the hours of response is .7 hours.

Status of the proposed information collection: Reinstatement without change.

Authority: Section 236 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended.