DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0362]

Draft Guidance for Industry on Stability Testing of Drug Substances and Drug Products; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to December 8, 1998, the comment period for the draft guidance for industry entitled ''Stability Testing of Drug Substances and Drug Products.'' The draft guidance provides recommendations regarding the stability studies that should be performed to support new drug applications (NDA's), abbreviated new drug applications (ANDA's), investigational new drug applications (IND's), biologics license applications (BLA's), product license applications (PLA's), and supplements to these applications. FDA published a notice of availability of the draft guidance in the **Federal Register** of June 8, 1998 (63 FR 31224). FDA is taking this action in response to several requests for an extension.

DATES: Written comments on the draft guidance may be submitted by December 8, 1998. General comments on the draft guidance are welcome at any time.

ADDRESSES: Copies of the draft guidance for industry are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kenneth J. Furnkranz, Center for Drug Evaluation and Research (HFD–625), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855–2737, 301–827–5848.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 8, 1998 (63 FR 31224), FDA published a notice announcing the availability of a draft guidance for industry entitled ''Stability Testing of Drug Substances and Drug Products.'' The draft guidance provides recommendations regarding the stability studies that should be performed to support NDA's, ANDA's, IND's, BLA's, PLA's, and supplements to these applications. Interested persons were given until September 9, 1998, to submit written comments on the draft guidance.

On June 18, 1998, FDA received a letter from Perrigo requesting that the agency extend the comment period on the draft guidance 120 days. On June 29, 1998, FDA received a letter from Pharmaceutical Research and Manufacturers of America requesting that the agency extend the comment period on the draft guidance 90 days.

This draft guidance is long and complex and introduces a number of new issues. Therefore the agency has decided to extend the comment period on the draft guidance to December 8, 1998, to allow the public more time to review and comment on its contents.

Interested persons may, on or before December 8, 1998, submit to the Dockets Management Branch (address above) written comments on the draft guidance. 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 are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 12, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–22565 Filed 8–21–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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

Periodically, the Health Resources and Services Administration publishes abstracts of information collection requests under review by the office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance request submitted to OMB for review, call the HRSA Reports Clearance Office at (301) 443–1129. The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: Evaluation of Health Care for the Homeless Program.—New—This is a request for approval to collect data to develop and test emergency department (ED) utilization rates as a measure of effectiveness of the Bureau of Primary Health Care's (BPHC) Health Care for the Homeless (HCH) program. The HCH Program is a Federal grant program authorized by section 330(h) of the Public Health Service Act. This program seeks to improve access by homeless individuals to primary health care and substance abuse treatment.

Data will be collected in five communities in which there are Health Care for the Homeless (HCH) grantees. Between 250–300 single homeless persons will be interviewed at soup kitchens in each of the five communities. The objective is a total sample of 1,350. There will be five categories of questions respondents will be asked: Emergency Room Visits, Inpatient Hospital Utilization, Outpatient Health Care Utilization, Health Status and Perceived Need for Health Care, and Demographics. Information from the study will be used in conjunction with data from ED records of homeless individuals with self reported ED use during the study period to determine whether particular ED visits should be considered ''appropriate or ''non-appropriate'.

The estimated reporting burden is as follows:

Type of report	Number of respondents	Minutes per response	Total burden hours
Individual	1,350	20	450

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Laura Oliven, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: August 17, 1998.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 98–22575 Filed 8–21–98; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of September 1998.

Name: National Advisory Council on the National Health Service Corps (NHSC).

Date and Time: September 9, 1998; 6:00 p.m.–9:00 p.m.; September 10–12, 1998; 9:00 a.m.–5:00 p.m.; September 13, 1998; 8:00 a.m.–11:00 a.m.

Place: Sheraton National Hotel, 900 South Orme Street, Arlington, VA 22204, (703) 521–1900.

The meeting is open to the public.

Agenda: Items will include, but not be limited to: In preparation for the year 2000 reauthorization the National Advisory Council has developed a draft position paper, ''The National Health Service Corps for the 21st Century.'' Reactions, suggestions and criticisms to this paper will be heard from public and private partners and other interested organizations on September 10–12. Copies of the draft paper will be available at the meeting. Other agenda items include updates on the NHSC program.

For further information, call Ms. Eve Morrow at (301) 594–4144.

Agenda items are subject to change as priorities dictate.

Dated: August 17, 1998.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 98–22574 Filed 8–21–98; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council; Notice of Meeting

In accordance with section 10(a) (2) of the Federal Advisory Committee Act (Pub. L. 92–463), announcement is made of the following National Advisory body scheduled to meet during the month of September 1998.

Name: National Advisory Committee on Rural Health.

Date and Time: September 13, 1998; 5:00 p.m.–6:30 p.m.; September 14–15, 1998; 8:30 a.m.–5:00 p.m.; September 16, 1998; 8:30 p.m.–11:30 a.m.

Place: Holiday Inn, Georgetown, 2101 Wisconsin Avenue, Washington, DC 20007, Phone: (202) 338–4600, FAX: (202) 333–6113.

The meeting is open to the public.

Agenda: A special session will be conducted on Sunday, September 13, for orientation of new members who were just appointed. Monday will include a panel discussion of ''Rural Researchers' Access to National Health Survey Data,'' a presentation and discussion of the new guidelines for designating HPSAs, and a report on ''Critical Access Hospitals.'' Tuesday will include legislative, telehealth, and regulatory updates. A presentation and discussion on the ''National Bipartisan Commission on the Future of Medicare'' will be followed by a discussion of Department interests and priorities for FY 1999. Agenda items are subject to change as priorities dictate.

Anyone requiring information regarding the subject Committee should contact Ms. Arlene A. Granderson, Office, or Rural Health Policy, Health Resources and Services Administration, Room 9–05, Parklawn Building, Rockville, Maryland 20857; telephone (301) 443–0835, FAX (301) 443–2803. Persons interested in attending any portion of the meeting or having questions regarding the meeting should contact Ms. Arlene Granderson or Ms. Lilly Smetana, Office of Rural Health Policy, Health Resources and Services Administration, telephone (301) 443–0835.

Dated: August 17, 1998.

Jane M. Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 98–22576 Filed 8–21–98; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Publication of OIG Compliance Program Guidance for Clinical Laboratories

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: This **Federal Register** notice sets forth the OIG's recently-issued Compliance Program Guidance for Clinical Laboratories. The OIG had previously developed and published a model compliance plan for the clinical laboratory industry on March 3, 1997. This Compliance Program Guidance for Clinical Laboratories is intended to be more consistent with compliance program guidances issued by the OIG with respect to the hospital industry and to home health agencies, and serves to clarify various aspects of the original model plan. As with previously-issued compliance program guidances, we believe that the development of this guidance for clinical laboratories will continue as a positive step towards promoting a higher level of ethical and lawful conduct throughout the entire health care community.

FOR FURTHER INFORMATION CONTACT: Christine Saxonis, Office of Counsel to the Inspector General, (202) 619–2078.

SUPPLEMENTARY INFORMATION: As part of a major initiative to engage the private health care community in combating fraud and abuse, the OIG developed and published in the **Federal Register** a model compliance plan for the clinical laboratories (62 FR 9435; March 3, 1997). The compliance plan was intended to provide clear guidance to that aspect of the clinical laboratory industry that was interested in reducing fraud and abuse within their organizations. Since that issuance, the OIG has developed and issued specific compliance program guidance for the hospital industry and for home health agencies.

This compliance program guidance is intended to refine and build on the original model guidance plan for clinical laboratories. In developing an effective compliance program, the OIG has identified 7 fundamental elements. They are:

- Implementing written policies, procedures and standards of conduct;
- Designing a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Enforcing standards through well-publicized disciplinary guidelines;
- Conducting internal monitoring and auditing; and
- Responding promptly to detected offenses and developing corrective action.

The development of this new Compliance Program Guidance for Clinical Laboratories has been enhanced