in Rockville, Maryland on December 14, 1999, to gather comments on the agency's proposed strategy.

DATES: Submit written comments at anytime.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the document. Submit written requests for single copies (on a 3.5″ diskette) of ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. Submit written comments concerning ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' to the Dockets Management Branch, (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Larry D. Spears, Center for Devices and Radiological Health (HFZ–340), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4646.

SUPPLEMENTARY INFORMATION:

I. Background

Reuse of SUD's is the practice of cleaning, disinfecting, sterilizing, and reusing medical devices that are intended for only one use. Reuse has raised concerns regarding patient safety, informed consent, and equitable regulation of reuse under the Federal Food, Drug, and Cosmetic Act. On May 5 and 6, 1999, FDA and AAMI cosponsored a conference on Reuse of Single-Use Devices to help examine policy alternatives regarding the practice of reuse. At that time, the agency committed to publishing a response to the positions expressed at the conference in the **Federal Register** by no later than October 1999. ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' is that response.

II. Significance of the Proposed Strategy Document

''FDA's Proposed Strategy on Reuse of Single-Use Devices'' represents options that the agency is considering on the reuse of single-use devices.

III. Electronic Access

In order to receive ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number 2525 followed by the pound sign (). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes ''FDA's Proposed Strategy on Reuse of Single-Use Devices,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

IV. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding this document. Submit two copies of any comments, except that individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. The agency will consider such comments when determining their final strategy. ''FDA's Proposed Strategy on Reuse of Single-Use Devices'' and any received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 28, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–28807 Filed 11–1–99; 12:19 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4114]

Draft ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors.'' The draft guidance document applies to the manufacture of gene therapy retroviral vector products intended for in vivo or ex vivo use and to followup monitoring of patients who have received retroviral vector products. When finalized, the draft guidance document is intended to supplement the guidance document entitled ''Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy,'' dated March 1998, and a letter to Sponsors of an IND Using Retroviral Vectors, dated September 20, 1993.

DATES: Written comments may be submitted at any time, however, comments should be submitted by February 1, 2000, to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors'' to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance document may also be obtained by mail by calling the CBER Voice Information System at 1–800–

835–4709 or 301–827–1800, or by fax by calling the FAX Information System at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Supplemental Guidance on Testing for Replication Competent Retrovirus in Retroviral Vector Based Gene Therapy Products and During Follow-up of Patients in Clinical Trials Using Retroviral Vectors.'' The draft guidance document applies to the manufacture of gene therapy retroviral vector products intended for in vivo or ex vivo use and to followup monitoring of patients who have received retroviral vector products. The draft document provides guidance for replication competent retrovirus (RCR) testing during manufacture, including timing, amount of material to be tested, and general testing methods. The draft document also provides guidance on monitoring patients for evidence of retroviral infection. When finalized, the draft guidance document is intended to supplement the guidance and recommendations pertaining to RCR testing given in the following documents: (1) ''Guidance for Industry: Guidance for Human Somatic Cell Therapy and Gene Therapy'' dated March 1998 (issued on the Internet); and (2) letter to Sponsors of an IND Using Retroviral Vectors, dated September 20, 1993.

The new recommendations are based on data and analyses generated by CBER and members of the gene therapy community. Public discussion and development of these recommendations have taken place during the retroviral breakout sessions at the ''1996 Gene Therapy Conference: Development and Evaluation of Phase I Products and Workshop on Vector Development'' (61 FR 18749, April 29, 1996), and the ''Forum 1997 Gene Therapy Conference.''

The draft guidance document represents the agency's current thinking regarding testing for RCR in retroviral vector based gene therapy products. It does not create or confer any rights for or on any person 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. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

The draft guidance document is being distributed for comment purposes only, and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Written comments may be submitted at any time, however, comments should be submitted by February 1, 2000, to ensure adequate consideration in preparation of the final document. 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. A copy of the draft guidance document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document using the World Wide Web (WWW). For WWW access, connect to CBER at ''http://www.fda.gov/cber/guidelines.htm''.

Dated: October 19, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–28560 Filed 11–2–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources And Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1891.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project

Querying the National Practitioner Data Bank—New.

Under the Health Resources and Services Administration (HRSA), Bureau of Health Professions (BHPr), the Division of Quality Assurance (DQA) is planning to conduct a survey to obtain information on the degree of user satisfaction with the National Practitioner Data Bank's (NPDB) reporting and querying processes, how users believe these processes can be improved, and how users perceive the usefulness of information they obtained from the NPDB for licensing and credentialing of health care entities, *e.g.* managed care organizations, State licensing boards for physicians and dentists, and professional societies. The study will also identify and survey non-user entities. The information obtained in this study will be interpreted in relation to similar information from previous studies conducted by DQA and the Office of the Inspector General.

The estimated response burden is as follows: