industry standard or a procedure at your facility. The draft guidance document also contains a biological product deviation reporting flowchart to aid in determining if an event is reportable.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance document represents the agency's current thinking with regard to the reporting of biological product deviations in manufacturing by blood and plasma establishments. 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 requirement of the applicable statutes and regulations. 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The draft document is being distributed for comment purposes only and is not intended for implementation at this time.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persons may submit to the Dockets Management Branch (address above) written or electronic comments regarding this draft guidance document. Submit written or electronic comments to ensure adequate consideration in preparation of the final document by November 13, 2001. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the 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 document at http://www.fda.gov/cber/guidelines.htm.

Dated: July 6, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–20157 Filed 8–10–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0221]

Draft ''Guidance for Industry: Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other Than Blood and Blood Components;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry: Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other Than Blood and Blood Components,'' dated August 2001. The draft guidance document provides licensed manufacturers of biological products other than blood and blood components with the agency's current thinking related to the biological product deviation reporting requirements. The draft guidance document will assist the licensed manufacturers of biological products other than blood and blood components in determining when a report is required, who submits the report, the timeframe for reporting, and how to submit the report.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by November 13, 2001. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance 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 the office in processing your requests. The 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 document to the Dockets Management Branch (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: Joseph L. Okrasinski, Jr., 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 document entitled ''Guidance for Industry: Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other Than Blood and Blood Components,'' dated August 2001. This draft guidance document is intended to provide assistance to licensed manufacturers of biological products other than blood and blood components regarding the reporting of any event associated with the manufacturing, testing, processing, packing, labeling, and storage, or with the holding or distribution of a biological product in which the safety, purity, or potency of a distributed product may be affected as required under § 600.14 (21 CFR 600.14) and 21 CFR 606.171 (65 FR 66621, November 7, 2000). The draft guidance document provides additional information regarding the regulations in § 600.14 which describe who must report, what must be included in the report, when the licensed manufacturer must report, and provide that the licensed manufacturer must report either electronically or by mail using a standardized reporting format. Examples of reportable and nonreportable events concerning incoming material specifications, process controls, product specifications, product testing, product labeling, quality control procedures, and product distribution are discussed. These examples may not apply to all establishments because they include deviations and unexpected events related to standard operating procedures implemented at individual establishments and may not be an industry standard or a procedure at your facility. The draft guidance document also contains a Biological Product Deviation Reporting Flowchart to aid in determining if an event is reportable.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance document represents the agency's current thinking with regard to the reporting of biological product deviations in the licensed

manufacturing of biological products other than blood and blood components. 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 requirement of the applicable statutes and regulations. 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

This draft 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 or electronic comments regarding this draft guidance document. Submit written or electronic comments to ensure adequate consideration in preparation of the final document by November 13, 2001. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the 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 at http://www.fda.gov/cber/guidelines.htm.

Dated: July 6, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–20158 Filed 8–10–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institute of Health

Public Health Service

The National Toxicology Program (NTP), National Institute of Environmental Health Sciences (NIEHS), Center for the Evaluation of Risks to Human Reproduction (CERHR) (1) announces an upcoming evaluation of 1-bromopropane (CASRN: 106–94–5) and 2-bromopropane (CASRN: 75–26–3), (2) solicits the nomination of individuals qualified to serve on an Expert Panel, and (3) requests public input on these chemicals.

Background

The NTP and the NIEHS established the NTP CERHR (**Federal Register**, Vol. 63, No. 239, page 68782) in June 1998. The purpose of the CERHR is to provide scientifically-based, uniform assessments of the potential for adverse effects on reproduction and development caused by agents to which humans may be exposed. A scientific expert panel reviews the scientific evidence on the chemical(s) under review, receives public comments, and then prepares a report on the chemical(s). The Expert Panel Report is made available for review and public comment on the CERHR web site (*http://cerhr.niehs.nih.gov*) and upon request from Dr. Michael Shelby, CERHR Director (see address below). Following the expert panel evaluation, the NTP staff prepares the NTP Center Report on the evaluated chemical(s). This report integrates background information on the chemical(s), findings of the expert panel, and a discussion of any pertinent studies published after the expert panel's evaluation. The NTP Center Report includes all public comments received on the Expert Panel Report. The NTP Center Report is made publicly available and is distributed to interested stakeholders and appropriate regulatory and research agencies. A summary of the complete review process was recently published in the **Federal Register** (Vol. 66, No. 136, pages 37047–37048) and can be found on the CERHR web site. A hardcopy may be requested from CERHR at the address given below.

Evaluation of 1- and 2-Bromopropane

1-Bromopropane (CASRN: 106–94–5) and 2-bromopropane (CASRN: 75–26–3) have been selected for the third CERHR expert panel evaluation. 1-Bromopropane is used as a spray adhesive; as a solvent for fats, waxes, or resins; and as an intermediate in the synthesis of other compounds. 2-Bromopropane is used in the synthesis of pharmaceuticals, dyes, and other compounds and is present as a contaminant in 1-bromopropane. Bromopropanes are being considered as replacement chemicals for hydrochlorofluorocarbons and chlorinated solvents. The scientific database on these chemicals includes studies on neurotoxicity, reproductive toxicity, and occupational exposures. 2-Bromopropane is reported to be a reproductive toxicant in humans. It is anticipated that the expert panel evaluation of 1- and 2-bromopropane will occur December 5–7, 2001, in Alexandria, VA.

An expert panel of approximately 12 scientists, selected for their scientific expertise in various aspects of reproductive and developmental toxicology and other relevant areas of science, will conduct these evaluations. The expert panel meeting will be open to the public with an opportunity scheduled for oral public comment.

Request for Public Input

(1) The CERHR invites input from the public on 1- and 2-bromopropane including toxicology information from completed and ongoing studies, information on planned studies, as well as current production data, human exposure information, use patterns, and environmental occurrence. Information and comments should be forwarded to Dr. Shelby at the address given below. Information and comments received by September 27, 2001 will be made available to CERHR staff and the Expert Panel and considered in the evaluation.

(2) The CERHR also invites nominations of qualified scientists to serve on the Bromopropane Expert Panel. Panelists are primarily drawn from the CERHR Expert Registry and/or the nomination of other scientists who meet the criteria for listing in that registry. Criteria for listing in the CERHR Expert Registry listing include: formal academic training and experience in a relevant scientific field, publications in peer-reviewed journals, membership in relevant professional societies, certification by an appropriate scientific Board or other entities, and participation in similar committee activities. Scientists on the expert panel will represent a wide range of expertise including developmental toxicology, reproductive toxicology, epidemiology, general toxicology, neurotoxicology, pharmacokinetics, exposure assessment, and biostatistics. Nominations received by September 27, 2001, publication will be considered for the Bromopropane Expert Panel and/or inclusion in the CERHR Expert Registry. Nominations should be forwarded to Dr. Shelby at the address given below.

Request for Nomination of Chemicals for Future CERHR Reviews

The CERHR welcomes the nomination of chemicals for possible future evaluation. The nominations can be made through the CERHR's web site (*http://cerhr.niehs.nih.gov*) or by contacting Dr. Shelby at the address given below.

Michael D. Shelby, Ph.D., Director, NTP Center for the Evaluation of Risks to Human Reproduction, 79 T.W.