By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket Nos. 98D–0316 and 98D–0317]**

### ''Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics Evaluation and Research (CBER) in Electronic Format-Biologics Marketing Applications [Biologics License Application (BLA), Product License Application (PLA)/ Establishment License Application (ELA) and New Drug Application (NDA)]''; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics and Research (CBER) in Electronic Format-Biologics Marketing Applications [Biologics License Application (BLA), Product License Application (PLA)/Establishment License Application (ELA) and New Drug Application (NDA)].'' The guidance document provides information regarding the electronic submission of license applications, i.e., BLA, PLA/ELA, NDA, and supplements and amendments to those applications intended for submission to Center for Biologics Evaluation and Research (CBER). This guidance document is part of CBER's effort to develop an efficient process for electronic submissions of regulatory information relating to the development and marketing of biological products. Submissions in electronic format are voluntary.

**DATES:** Written comments may be submitted at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance entitled ''Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics and Research (CBER) in Electronic Format-Biologics Marketing Applications [Biologics License Application (BLA), Product License Application (PLA)/Establishment License Application (ELA) and New Drug Application (NDA)]'' 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 guidance document.

Submit written comments on the 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:** Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 400N, Rockville, MD 20852–1448, 301–827–6210.

**SUPPLEMENTARY INFORMATION:**

## I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Providing Regulatory Submissions to the Center for Biologics and Research (CBER) in Electronic Format-Biologics Marketing Applications [Biologics License Application (BLA), Product License Application (PLA)/Establishment License Application (ELA) and New Drug Application (NDA)].'' This guidance document is intended to provide a degree of uniformity for electronically submitted biologics marketing applications to assure timely review, archiving, and retrieval processes for agency reviewers, and to describe those electronic formats that CBER is currently able to support for review and archive purposes. The guidance announced in this notice finalizes the two draft guidances entitled ''Draft Guidance for Industry: Electronic Submissions of a Biologics License Application (BLA) or Product License Application (PLA)/ Establishment License Application (ELA) to the Center for Biologics Evaluation and Research,'' and ''Draft 'Guidance for Industry: Electronic Submissions of Case Report Forms (CRF's), Case Report Tabulations (CRT's) and Data to the Center for Biologics Evaluation and Research,''' which were announced in the **Federal Register** of June 1, 1998 (63 FR 29741 and 29739, respectively). In the **Federal Register** of January 28, 1999 (64 FR 4433), FDA announced the availability of a document entitled ''Guidance for Industry on General Considerations for Providing Regulatory Submissions in Electronic Format'' which provided a list of guidance documents that are under development regarding electronic submissions, and guidance on general issues relevant to all electronic submissions.

In the **Federal Register** of March 20, 1997 (62 FR 13430), FDA published the electronic records; electronic signatures final rule, which provided for the voluntary submission of parts or all of an application, as defined in the relevant regulations, in electronic format without an accompanying paper copy (21 CFR part 11). FDA also established public docket number 92S–0251 to provide a permanent location for a list of the agency units that are prepared to receive electronic submissions and the specific types of regulatory records that can be accepted in electronic format (62 FR 13467, March 20, 1997). CBER will identify in this public docket any submission type that can be reviewed and archived in an electronic format as they become available. This public docket can be accessed on the Internet at http://www.fda.gov/ohrms/dockets/dockets/92s0251/92s0251.htm.

This guidance document represents the agency's current thinking with regard to regulatory submissions in electronic format. 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 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

Interested persons, may at any time, submit written comments to the Dockets Management Branch (address above) regarding this guidance document. 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: November 5, 1999.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

**[Docket Nos. 99D–4575 and 99D–4576]**

## Draft Guidances for Industry on Food-Contact Substance Notification System; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of two draft guidance documents entitled ''Preparation of Premarket Notifications for Food Contact Substances: Chemistry Recommendations,'' and ''Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations.'' These documents are intended to provide guidance for industry regarding the preparation of premarket notifications (PMN's) for food-contact substances (FCS's). In addition, FDA Form No. 3480 entitled ''Notification for New Use of a Food Contact Substance'' is being made available as an attachment to each of these guidance documents. This form is provided for comment as part of the collection of information for the notification system for FCS's. FDA is providing these draft guidances as part of its implementation of the PMN process for FCS's established by the FDA Modernization Act of 1997 (FDAMA) (Public Law 105–115).

**DATES:** Submit written comments concerning these draft guidances by February 14, 2000. Submit written comments concerning the collection of information by January 11, 2000.

**ADDRESSES:** Submit written comments concerning these draft guidances and the collection of information 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. Submit written requests for single copies of the draft guidances to the Office of Premarket Approval (HFS–200), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3100, FAX 202–418–3131. All requests should identify the draft guidances by the titles listed above. See the **SUPPLEMENTARY INFORMATION** section for electronic access to these draft guidances.

**FOR FURTHER INFORMATION CONTACT:** Mitchell A. Cheeseman, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3083.

**SUPPLEMENTARY INFORMATION:**

### I. Background

FDAMA amended section 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348) to establish a PMN process as the primary method for authorizing new uses of food additives that are FCS's. A ''food contact substance'' is defined in section 409(h)(6) of the act as ''any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'' Once the PMN process begins to operate (see section 409(h)(5) of the act), FDA expects most new uses of FCS's that previously would have been regulated by issuance of a listing regulation in response to a food additive petition (FAP) or would have been exempted from the requirement of a regulation under the threshold of regulation (TOR) process will be the subject of PMN's. FDA is announcing the availability of two draft guidance documents entitled ''Preparation of Premarket Notifications for Food Contact Substances: Chemistry Recommendations,'' and ''Preparation of Premarket Notifications for Food Contact Substances: Toxicology Recommendations.'' These documents are intended to provide guidance for industry regarding the preparation of PMN's for FCS's. FDA is providing these draft guidances as part of its implementation of the PMN process for FCS's established by FDAMA.

### II. Significance of Guidance

These two draft guidance documents represent the agency's current thinking on the data and information that should be submitted in a PMN for the use of an FCS. These draft guidance documents do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations. These two draft guidance documents are level 1 guidances under the agency's good guidance practices (62 FR 8961, February 27, 1997).

### III. Electronic Access

The draft guidances may also be accessed via the Internet at the Center for Food Safety and Applied Nutrition website at http://www.fda.gov/cfsan.

### IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

*Title*: Food-Contact Substances Notification System

*Description*: Section 409(h) of the Federal Food, Drug, and Cosmetic Act (the act) establishes a premarket notification process for FCS's. Section 409(h)(6) of the act defines a ''food contact substance'' as ''any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'' Section 409(h)(3) of the act requires that the notification process be