submitting a certificate for signature to FDA is aware of and knows that they are subject to the provisions of section 1001 of Title 18, U.S. Code. This law provides that it is a criminal offense to knowingly and willfully make a false statement or alter or counterfeit documents in a matter within the jurisdiction of a U.S. agency.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Products	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Shell Eggs	20	1	20	0.25	5
Dairy	100	1	100	0.25	25
Game Meat and Meat Products	20	1	20	0.25	5
Animal Casings	15	1	15	0.25	3.75
Total					38.75

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated number of respondents is based on volume of exports and responses received to date. The estimated number of yearly responses has been decreased from the estimate in FDA's previous notice seeking comment on this collection of information (61 FR 66671, December 18, 1996) because the actual number of responses received has been decreasing. Companies do not need to reapply unless they have a compliance problem. An estimate for processors that export animal casings has also been added because these processors are now being included in the listing process. Finally, the operating and maintenance cost estimate included in the previous notice has been removed because, according to OMB's draft guidance on interpretation of the PRA, the costs listed were not operating and maintenance costs. The costs are now listed in FDA's supporting statement in the ''Other Non-Labor Costs'' category. A copy of the supporting statement may be obtained from the contact person listed above.

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN (THIRD PARTY DISCLOSURE)[1]

Respondents	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Trade Association	14	1	14	8	112
State	50	1	50	8	400
Total					512

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimated for the trade associations assumes the trade associations will disseminate FDA's information request through mass mailings to their membership or publish it in their trade magazine or newsletter. The burden estimated for State authorities assumes dissemination of information to the processors or dissemination of information about the processors to FDA.

Dated: May 21, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–14297 Filed 5–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0317]

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;'' 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: Electronic Submissions of Case Report Forms (CRF's), Case Report Tabulations (CRT's) and Data to the Center for Biologics Evaluation and Research.'' This draft guidance document, when finalized, is intended to provide guidance to industry regarding the submission of electronic CRF's and CRT's as part of license applications to the Center for Biologics Evaluation and Research (CBER). This draft guidance document is part of CBER's effort to provide 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, however comments should be submitted by July 31, 1998, 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: Electronic Submissions of Case Report Forms (CRF's), Case Report Tabulations (CRT's) and Data to the Center for Biologics Evaluation and Research'' 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 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, 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: Electronic Submissions of Case Report Forms (CRF's), Case Report Tabulations (CRT's) and Data to the Center for Biologics Evaluation and Research.'' The draft guidance document is intended to describe those electronic formats that CBER is currently able to support for review and archive of CRF's and CRT's. This draft guidance document supersedes two previous draft guidance documents entitled ''Guidance for Industry: Electronic Submissions of Case Report Forms and Case Report Tabulations'' (November 1996), and ''Guidance for Industry: Submitting Application Archival Copies in Electronic Format'' (November 1996).

This draft guidance document represents the agency's current thinking on electronic submissions of case report forms, case report tabulations and data to CBER. 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. This draft guidance document applies only to submissions made to CBER and not to the Center for Drug Evaluation and Research.

II. Request for Comments

This 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 July 31, 1998, to ensure adequate consideration in preparation of the final 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 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: May 22, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–14310 Filed 5–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0314]

Draft Guidance for Industry: Pilot Program for Electronic Investigational New Drug (eIND) Applications for Biological Products; 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: Pilot Program for electronic Investigational New Drug (eIND) Applications for Biological Products.'' This draft document, when finalized, is intended to provide guidance to sponsors on the design, development, organization, and submission of an eIND application to the Center for Biologics Evaluation and Research (CBER) as part of a pilot eIND program. This draft document is part of CBER's effort to develop, in cooperation with sponsors, 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, however, comments should be submitted by July 31, 1998, 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: Pilot Program for electronic Investigational New Drug (eIND) Applications for Biological Products'' 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. Submit written comments on the draft guidance document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Astrid L. Szeto, 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: Pilot Program for electronic Investigational New Drug (eIND) Applications for Biological Products.'' This draft guidance document, when finalized, is intended to provide sponsors guidance on the design, development, organization, and submission of eIND applications. This draft guidance document does not address the scientific, clinical, and regulatory requirements of preparing an IND submission. These requirements can be found in Title 21 of the Code of Federal Regulations, part 312 (21 CFR