respondent to file compliance reports, retain certain documents, and notify the Commission of certain changes in its corporate structure.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 98–14420 Filed 5–29–98; 8:45 am]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics; Meetings

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services announces the following advisory committee meetings.

Name: National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Health Data Needs, Standards, and Security.

Times and Dates: 10:00 a.m.-5:00 p.m., June 15, 1997.

Place: Room 505A, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201.

Status: Open.

Purpose: Under the Administrative Simplification provisions of Pub. L. 104–191, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the Secretary of Health and Human Services is required to adopt standards for specified transactions to enable health information to be exchanged electronically. The law requires that, within 24 months of adoption, all health plans, health care clearinghouses, and health care providers who choose to conduct these transactions electronically must comply with these standards. The law also requires the Secretary to adopt a number of supporting standards including standards for code sets and classifications systems. The Secretary is required to rely upon the recommendations of the National Committee on Vital and Health Statistics (NCVHS) in complying with these provisions. The NCVHS is the Department's federal advisory committee on health data, privacy and health information policy.

On June 15, 1998, the NCVHS Subcommittee on Health Data Needs, Standards, and Security will hold a meeting to review the progress of its work and plan future activities. The Subcommittee will discuss plans for addressing 1) the HIPAA requirements relating to electronic data interchange standards for claims attachments and 2) NCVHS recommendations for standards for clinical data and its electronic interchange. The Subcommittee also will consider possible comments on the published Notices of Proposed Rulemaking relating to the adoption of EDI standards for health care administrative transactions. In addition, the Subcommittee will discuss approaches to the development of a framework for procedure classification systems, as well as plans for public hearings on unique individual identifiers for use in the health system. All topics and times are tentative and subject to change. Please check the NCVHS website, where a detailed agenda will be posted prior to the meeting.

Contact Person for More Information: Substantive program information as well as summaries of NCVHS meetings and a roster of committee members may be obtained by visiting the NCVHS website (http://aspe.os.dhhs/gov/ncvhs). You may also call James Scanlon, NCVHS Executive Staff Director, Office of the Assistant Secretary for Planning and Evaluation, DHHS, Room 440–D. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201, telephone (202) 690–7100, or Marjorie S. Greenberg, Executive Secretary, NCVHS, NCHS, CDC, Room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone (301) 436–7050.

Note: In the interest of security, the Department has instituted stringent procedures for entrance into the Hubert H. Humphrey Building by non-government employees. Thus, individuals without government identification cards may need to have the guard call for an escort to the meeting room.

Dated: May 26, 1998.

James Scanlon,

Director, Division of Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 98–14291 Filed 5–29–98; 8:56 am]

BILLING CODE 4151–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96N–0373]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by July 1, 1998.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Request for Information From U.S. Processors that Export to the European Community (OMB Control Number 0910–0320—Reinstatement)

European Community (EC) is a group of 15 European countries that have agreed to harmonize their commodity requirements to facilitate commerce among member States. EC legislation for intra-EC trade has been extended to trade with non-EC countries, including the United States. For certain food products, including those listed below, EC legislation requires assurances from the responsible authority of the country of origin that the processor of the food is in compliance with applicable regulatory requirements.

With the assistance of trade associations and State authorities, FDA requests information from processors that export certain animal-derived products (e.g., shell eggs, dairy products, game meat, game meat products, and animal casings) to EC. FDA uses the information to maintain lists of processors that have demonstrated current compliance with U.S. requirements and provides the lists to EC quarterly. Inclusion on the list is voluntary. EC member countries refer to the lists at ports of entry to verify that products offered for importation to EC from the United States are from processors that meet U.S. regulatory requirements. Products processed by firms not on the list are subject to detention and possible refusal at the port. FDA requests the following information from each processor:

(1) Business name and address;

(2) Name and telephone number of person designated as business contact;

(3) Lists of products presently being shipped to EC and those intended to be shipped in the next 6 months;

(4) Name and address of manufacturing plants for each product;

(5) Names and affiliations of any Federal, State, or local governmental agencies that inspect the plant, government-assigned plant identifier, such as plant number, and last date of inspection; and

(6) Assurance that the firm or individual representing the firm and

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,