shall notify the Commission as follows: (1) file with the secretary of the Commission a detailed petition, supported by an affidavit, that states with specificity the basis for any claim that it has failed to act; and (2) serve the state commission and other parties to the proceeding on the same day that the party serves the petition on the Commission. Within 15 days of the filing of the petition, the state commission and parties to the proceeding may file a response to the petition.

OMB Control No.: 3060–0439.

Title: Regulations Concerning Indecent Communications by Telephone.

Form No.: N/A.

Type of Review: Extension.

Respondents: Business or other for profit.

Number of Respondents: 10,200.

Estimated Time Per Response: .13 hours per response (avg) (about 8 minutes).

Total Annual Burden: 1,632 hours.

Estimated Annual Reporting and Recordkeeping Cost Burden: 0.

Frequency of Response: On occasion.

Needs and Uses: Section 223 requires telephone companies, to the extent technically feasible, to prohibit access to indecent communications from the telephone of a subscriber who has not previously requested access. Section 64.201 implements Section 223 and contains several information collection requirements: (1) A requirement that certain common carriers block access to indecent messages unless the subscriber seeks access from the common carrier (telephone company) in writing; (2) a requirement that adult message service providers notify their carriers of the nature of their programming; and (3) a requirement that a provider of adult message services request that their carriers identify it as such in bills to its subscribers. The information requirements are imposed on carriers, adult message service providers, and those who solicit their services to ensure that minors are denied access to material deemed indecent. The information collections are necessary for the Commission to fulfill its mandate under Section 223 of the Communications Act.

Federal Communications Commission.

Magalie Roman Salas,

Secretary.

[FR Doc. 00–32787 Filed 12–22–00; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of a Matter To Be Added to the Agenda for Consideration at an Agency Meeting

Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that the following matter will be added to the ''discussion agenda'' for consideration at the open meeting of the Board of Directors of the Federal Deposit Insurance Corporation scheduled to be held at 10:00 a.m. on Thursday, December 21, 2000, in the Board Room on the sixth floor of the FDIC Building located at 550—17th Street, NW., Washington, DC:

Memorandum and resolution re: Disclosure and Reporting of Community; Reinvestment Act-Related Agreements: Joint Final Rule.

Requests for further information concerning the meeting may be directed to Mr. Robert E. Feldman, Executive Secretary of the Corporation, at (202) 898–6757.

Federal Deposit Insurance Corporation.

Dated: December 20, 2000.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 00–32915 Filed 12–21–00; 8:45 am]

BILLING CODE 6714–01–M

GENERAL SERVICES ADMINISTRATION

Proposed Collection; Comment Request Entitled Nondiscrimination in Federal Financial Assistance Programs

AGENCY: Office of Equal Employment Opportunity, GSA.

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance (3090–0228).

SUMMARY: The GSA hereby gives notice under the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), that it is requesting the Office of Management and Budget (OMB) to reinstate information collection, 3090–0228, ''Nondiscrimination in Federal Financial Assistance Programs.'' This information is needed to ensure that recipients of Federal financial assistance distribute Federal surplus property in a nondiscriminatory manner.

DATES: January 25, 2001.

ADDRESSES: Send comments to Edward Springer, GSA Desk Officer, Room 3235, NEOB, Washington, DC 20503.

Annual Reporting Burden: Respondents: 55; annual responses: 1; average hours per response: 16; burden hours: 16,200.

FOR FURTHER INFORMATION CONTACT: William Conley, Office of Equal Employment Opportunity, (202) 501–0767.

Copy of Proposal: A copy of this proposal may be obtained from the GSA Acquisition Policy Division (MVP), Room 4011, GSA Building, 18th & F Streets NW, Washington, DC 20405, or by telephoning (202) 501–3822, or by faxing your request to (202) 501–3341.

Dated: December 19, 2000.

David A. Drabkin,

Deputy Associate Administrator, Office of Acquisition Policy.

[FR Doc. 00–32841 Filed 12–22–00; 8:45 am]

BILLING CODE 6820–61–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1502]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Adverse Experience Reporting for Licensed Biological Products, and General Records

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.

DATES: Submit written comments on the collection of information by January 25, 2001.

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: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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

Adverse Experience Reporting for Licensed Biological Products; and General Records--21 CFR 600.12 and Part 600 Subpart D (OMB Control Number 0910-0308)--Extension

Under the Public Health Service Act (42 U.S.C. 262), FDA is required to ensure the marketing of only those biological products which are safe and effective. FDA must therefore be informed of all adverse experiences occasioned by the use of licensed biological products. FDA issued the adverse experience reporting (AER) requirements to enable FDA to take actions necessary for the protection of the public health in response to reports of adverse experiences related to licensed biological products. The primary purpose of FDA's AER system is to flag potentially serious safety problems with licensed biological products, focusing especially on newly licensed products. Although premarket testing discloses a general safety profile of a new drug's comparatively common adverse effects, the larger and more diverse patient populations exposed to the licensed biological product provides the opportunity to collect information on rare, latent, and long-term effects. Reports are obtained from a variety of sources, including patients, physicians, foreign regulatory agencies, and clinical investigators. Information derived from the AER system contributes directly to increased public health protection because such information enables FDA to recommend important changes to the product's labeling (such as adding a new warning), to initiate removal of a biological product from the market when necessary, and to ensure the manufacturer has taken adequate corrective action if necessary.

Section 600.80(c)(1) (21 CFR 600.80(c)(1)) requires the licensed manufacturer to report each adverse experience that is both serious and unexpected, regardless of source, as soon as possible but in any case within 15 working days of initial receipt of the information. Section 600.80(e) requires licensed manufacturers to submit a 15-day alert report obtained from a postmarketing clinical study only if there is a reasonable possibility that the product caused the adverse experience. Section 600.80(c)(2) requires the licensed manufacturer to report each adverse experience not reported under paragraph (c)(1) at quarterly intervals, for 3 years from the date of issuance of the product license, and then at annual intervals. The majority of the periodic reports will be submitted annually since a large percentage of the current licensed biological products have been licensed longer than 3 years. Section 600.80(i) requires the licensed manufacturer to maintain for a period of 10 years records of all adverse experiences known to the licensed manufacturer, including raw data and any correspondence relating to the adverse experiences. Section 600.81 (21 CFR 600.81) requires the licensed manufacturer to submit information about the quantity of the product distributed under the product license, including the quantity distributed to distributors at an interval of every 6 months. The semiannual distribution report informs FDA of the quantity, the lot number, and the dosage of different products. Section 600.90 (21 CFR 600.90) requires a licensed manufacturer to submit a waiver request with supporting documentation when asking for waiving the requirement that applies to them under §§ 600.80 and 600.81.

Manufacturers of biological products for human use must keep records of each step in the manufacture and distribution of products including recalls of the product. The recordkeeping requirements serve preventative and remedial purposes. These requirements establish accountability and traceability in the manufacture and distribution of products, and enable FDA to perform meaningful inspections.

Section 600.12 (21 CFR 600.12) requires that all records of each step in the manufacture and distribution of a product be made and retained for no less than 5 years after the records of manufacture have been completed or 6 months after the latest expiration date for the individual product, whichever represents a later date. In addition, records of sterilization of equipment and supplies, animal necropsy records, and records in cases of divided manufacturing of a product are required to be maintained. Section 600.12(b)(2) requires complete records to be maintained pertaining to the recall from distribution of any product.

Respondents to this information collection are manufacturers of biological products. In fiscal year (FY) 99 there were approximately 79 licensed manufacturers. This number excludes those manufacturers who produce blood and blood components and in vitro diagnostic licensed products because they are specifically exempt from the regulations. However, not all manufacturers may have any submissions in a given year and some may have multiple submissions. FDA received four waiver requests under § 600.90, of which one was approved for exemption of the AER requirements. In FY 99, there were an estimated 3,662 15-day alert reports, 13,238 periodic reports, and 502 distribution reports submitted to FDA. The number of 15-day alert reports for postmarketing studies as stated in § 600.80(e) was minimal and is included in the total number of 15-day alert reports. The hours per response are based on FDA experience. The burden hours required to complete the MedWatch Form for § 600.80(c)(1), (e), and (f) are reported under OMB Control No. 0910-0291.

In the Federal Register of September 25, 2000 (65 FR 57612), the agency requested comments on the proposed collection of information. No significant comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
600.80(c)(1) and (e)	78	46.95	3,662	1	3,662
600.80(c)(2)	78	169.72	13,238	1	13,238
600.81	78	6.4	502	1	502
600.90	4	1	4	1	4
Total					17,407

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

There are approximately 343 licensed manufacturers of biological products. However, the number of recordkeepers listed for § 600.12(a) through (e) excluding paragraph (b)(2) is estimated to be 111. This number excludes

manufacturers of blood and blood components because their burden hours for recordkeeping have been reported under § 606.160 in OMB Control No. 0910-0116. The recordkeeping burden is based on the number of lots released (6,446), the number of recalls made (1,176), and the total number of AER reports received (16,900) for FY 99. The hours per record are based on FDA experience.

FDA estimates the burden of this recordkeeping as follows:

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record-keeper	Total Hours
600.12	111	58.1	6,446	32	206,272
600.12(b)(2)	343	3.4	1,176	24	28,224
600.80(i)	79	213.92	16,900	1	16,900
Total					251,396

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

Dated: December 18, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–32783 Filed 12–22–00; 8:45 am]

BILLING CODE: 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1501]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Threshold of Regulation for Substances Used in Food-Contact Articles

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.

DATES: Submit written comments on the collection of information by January 25, 2001.

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: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy 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 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Threshold of Regulation for Substances used in Food-Contact Articles--21 CFR 170.39 (OMB Control Number 0910-0298)—Extension

Under section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)), the use of a food additive is deemed unsafe unless: (1) It conforms to an exemption for investigational use under 409(j); (2) it conforms to the terms of a regulation prescribing its use; or (3) in the case of a food additive which meets the definition of a food-contact substance in section 409(h)(6), there is either a regulation authorizing its use in accordance with section 409(a)(3)(A) or an effective notification in accordance with section 409(a)(3)(B).

In the **Federal Register** of July 17, 1995 (60 FR 36582), § 170.39 (21 CFR 170.39) established a process that provides the manufacturer with an opportunity to demonstrate that the likelihood or extent of migration to food of a substance used in a food-contact article is so trivial that the use need not be the subject of a food additive listing regulation or an effective notification. The agency has established two thresholds for the regulation of substances used in food-contact articles. The first exempts those substances used in food-contact articles where the resulting dietary concentration would be at or below 0.5 parts per billion. The second exempts regulated direct food additives for use in food-contact articles where the resulting dietary exposure is 1 percent or less of the acceptable daily intake for these substances.

In order to determine whether the intended use of a substance in a food-contact article meets the threshold criteria, certain information specified in § 170.39(c) must be submitted to FDA. This information includes: (1) The chemical composition of the substance for which the request is made; (2) detailed information on the conditions of use of the substance; (3) a clear statement of the basis for the request for exemption from regulation as a food additive; (4) data that will enable FDA to estimate the daily dietary concentration resulting from the proposed use of the substance; (5) results of a literature search for toxicological data on the substance and its impurities; and (6) information on the environmental impact that would result from the proposed use.

FDA uses this information to determine whether the food-contact article meets the threshold criteria. Respondents to this information collection are individual manufacturers and suppliers of substances used in food-contact articles (i.e., food packaging and food processing equipment) or of the articles themselves.

In the **Federal Register** of September 19, 2000 (65 FR 56585), the agency requested comments on the proposed collection of information. No comments were received.

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