year on compliance with the Rule, for a total estimate of 16,213,300 burden hours.

No provisions in the Mail or Telephone Order Merchandise Rule have been amended or changed in any manner. All of the requirements relating to disclosure and notification remain the same. We have, however, reduced the 1995 total burden estimate of 16,213,300 hours for the reasons discussed below.

In the OMB regulation implementing the PRA, *burden* is defined to exclude any effort that would be expended regardless of any regulatory requirement. 5 CFR 1320.3(b)(2). In past rulemaking proceedings, industry trade associations and individual witnesses have testified that compliance with the Rule is now widely regarded by direct marketers as being good business practice. The Rule's notification requirements would be followed in any event by most merchants to meet consumer expectations with respect to timely shipment, notification of delay, and prompt and full refunds. Providing consumers with notice about the status of their orders fosters consumer loyalty and encourages repeat purchases that are important to the success of direct marketers. Thus, much of the time and expense associated with Rule compliance is not properly treated as burden under the PRA.

In estimating any remaining burden, the agency has considered ''the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose or provide information to or for a Federal agency.'' 5 CFR 1320.3(b)(1). This includes ''developing, acquiring, installing, and utilizing technology and systems for the purpose of disclosing and providing information.'' 5 CFR 1320.3(b)(1)(iv). Although not expressly stated in the regulation, it seems reasonable to infer that the definition of *burden* would include upgrading and maintaining computer systems used to comply with the Rule's requirements.

The mail order industry has been subject to the basic provisions of the Rule since 1976 and the telephone order industry since 1994. Thus, businesses have had several years (and some have had decades) to integrate compliance systems into their business procedures. Nonetheless, staff has allocated some hours, estimated at 150 hours annually per company, toward the maintenance of computer systems by the affected companies, even though maintenance and upkeep arguably would also be part of ordinary business practice in the industry.

Further, in our best judgment (more accurate data from the industry is not currently available), approximately 1,000 new companies have entered the market since 1995. Thus, the current total affected firms would consist of approximately 71,560 companies. Additionally, staff estimates that the approximately 1,000 new companies enter the covered market each year. Further, we estimate that new companies entering the market would need 230 hours per year (1995 figure of 229.78 rounded to 230) for compliance measures associated with system start-up, although again, it could be argued that such efforts would be undertaken even absent the Rule. We have therefore estimated that the total burden for compliance with the Rule would be approximately 10,964,000 hours. (1,000×230=230,000)+ (71,560×150=10,734,000.)

To emphasize, the FTC has not amended, nor is it in the process of amending, the Mail or Telephone Order Merchandise Rule. The burden hours associated with the Rule have been recalculated because the originally-estimated hours included one-time start up tasks (i.e., implementing systems and processes to meet the Rule's requirements) that have now been completed by most of the affected companies.

FOR FURTHER INFORMATION CONTACT: Elaine W. Crockett (202) 326–2453; FAX (202) 326–2447; E-mail: ecrockett@ftc.gov.

Jay C. Shaffer,

Acting General Counsel.

[FR Doc. 97–23311 Filed 9–2–97; 8:45 am]

BILLING CODE 6750–01–M

FEDERAL TRADE COMMISSION

Sunshine Act Meeting

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 62 F.R., Friday, August 22, 1997, Page No. 44698.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 10:00 a.m., Wednesday, September 4, 1997.

CHANGES IN THE AGENDA: The Federal Trade Commission has canceled its previously scheduled Oral Argument meeting for September 4, 1997, at 10:00 a.m.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 97–23385 Filed 8–28–97; 4:11 pm]

BILLING CODE 6750–01–M

FEDERAL TRADE COMMISSION

Sunshine Act Meeting

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 62 F.R., Friday, August 22, 1997, Page No. 44698.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: 2:00 p.m., Wednesday, September 3, 1997.

CHANGES IN THE AGENDA: The Federal Trade Commission has cancelled its previously scheduled Oral Argument meeting for September 3, 1997, at 2:00 p.m.

Benjamin I. Berman,

Acting Secretary.

[FR Doc. 97–23527 Filed 8–29–97; 3:28 pm]

BILLING CODE 6750–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

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

The Department of Health and Human Services, Office of the Secretary publishes a list of information collections it has submitted to the Office of Management and Budget (OMB) for clearance in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) and 5 CFR 1320.5. The following are those information collections recently submitted to OMB.

1. Information Collection Requirements Contained in 42 CFR part 1004 (Revised Peer Review Organization Sanctions for Failing to Meet Statutory Obligations)—This information collection requirement is necessary to enable a Peer Review Organization (PRO) to submit a report and recommendation to the OIG if PRO-identified violations have not been resolved. In addition, an alternative sanctions notification process provides sanctioned practitioners or other persons the option of informing patients directly to the sanction action taken against them.—*Respondents:* Individuals, Business or other for-profit; Not-for-profit institutions—Burden Information for the PRO Report—*Annual Responses:* 7;*Annual Burden per Response:* 4 hours;*Annual Burden for PRO Report:* 28 hours—Burden Information for the Sanction Notification—*Annual Responses:* 5;*Annual Burden per Response:* 2 hours;*Annual Burden for Sanction Notification:* 10 hours—*Total Burden:* 38 hours.

OMB Desk Officer: Allison Eydt.

Copies of the information collection packages listed above can be obtained by calling the OS Reports Clearance Officer on (202) 690–6207. Written comments and recommendations for the proposed information collection should be sent directly to the OMB desk officer designated above at the following address: Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503.

Comments may also be sent to Cynthia Agens Bauer, OS Reports Clearance Officer, Room 503H, Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. Written comments should be received within 30 days of this notice.

Dated: August 27, 1997.

William R. Beldon,

Acting Deputy Assistant Secretary, Budget.

[FR Doc. 97–23304 Filed 9–2–97; 8:45 am]

BILLING CODE 4150–04–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Two Meetings of the National Bioethics Advisory Commission (NBAC): One Each of its Genetics and Human Subjects Subcommittees

SUMMARY: Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is given of two meetings of the National Bioethics Advisory Commission. Commission members will solicit testimony on the protection of the rights and welfare of human subjects in research including decisionally and/or cognitively impaired populations and will address the use of genetic information involved in tissue storage. The meetings are open to the public and opportunities for statements by the public will be provided.

DATES/TIMES/LOCATIONS:

Human Subjects Subcommittee

September 18, 1997, 8:15 am–5:30 pm, (9:00 am–12 noon public hearing)—National Institutes of Health, 9000 Rockville Pike, Building 31, 6th Floor, Conference Room 10, Bethesda, Maryland 20892

Genetics Subcommittee

September 18, 1997, 3:00 pm–5:30 pm—National Institutes of Health, 9000 Rockville Pike, Building 31, 6th Floor, Conference Room 9, Bethesda, Maryland 20892

September 19, 1997, 8:30 am–12:30 pm—Same Location as Above

SUPPLEMENTARY INFORMATION: The President established the National Bioethics Advisory Commission (NBAC) by Executive Order 12975 on October 3, 1995. The mission of the NBAC is to advise and make recommendations to the National Science and Technology Council and other entities on bioethical issues arising from the research on human biology and behavior, and in the applications of that research including clinical applications.

Public Participation

All meetings are open to the public with attendance limited by the availability of space. On September 18, 1997, the Human Subjects Subcommittee of the National Bioethics Advisory Commission will discuss possible guidelines for research involving decisionally or cognitively impaired subjects, and public testimony is invited on the ethical issues of such research. A public hearing will be held on ethical issues in research involving decisionally or cognitively impaired individuals from 9:00 am—12 noon on September 18, 1997. Members of the public who wish to present oral statements should contact the Deputy Executive Director of the NBAC by telephone, fax machine, or mail as shown below prior to the meeting as soon as possible. Individuals unable to make oral presentations are encouraged to mail or fax their comments to the NBAC staff office for distribution to the subcommittee members or Commission and inclusion in the public record.

Persons needing special assistance, such as sign language interpretation or other special accommodations, should contact NBAC staff at the address or telephone number listed below as soon as possible.

FOR FURTHER INFORMATION CONTACT: Ms. Henrietta D. Hyatt-Knorr, National Bioethics Advisory Commission, MSC–7508, 6100 Executive Boulevard, Suite 5B01, Rockville, Maryland 20892–7508, telephone 301–402–4242, fax number 301–480–6900.

Dated: August 28, 1997.

Henrietta D. Hyatt-Knorr,

Deputy Executive Director, Acting, National Bioethics Advisory Commission.

[FR Doc. 97–23377 Filed 9–2–97; 8:45 am]

BILLING CODE 4160–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0353]

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 October 3, 1997.

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

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, 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:

Food Additives and Food Additive Petitions (21 CFR Parts 171, 172, 173, 175 to 178, and 180) (OMB Control Number 0910–0016—Reinstatement)

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348(a)) provides that any particular use or intended use of a food additive shall be deemed to be unsafe, unless the additive and its use or intended use are in conformity with a regulation issued under section 409 of the act that describes the condition(s) under which the additive may be safely used, or unless the additive and its use or intended use conform to the terms of an exemption for investigational use. Food additive petitions are submitted by individuals or companies to obtain approval of a new food additive or to amend the conditions of use permitted under an existing food additive regulation. Section 171.1 (21 CFR 171.1)