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

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.


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.


Henrietta D. Hyatt-Knorr,
Deputy Executive Director, Acting, National Bioethics Advisory Commission.

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)