DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4329]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Filing Objections and Requests for a Hearing on a Regulation or Order

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 March 30, 2000.

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.

Filing Objections and Requests for a Hearing on a Regulation or Order

Under section 701(e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(e)(2)), within 30 days after publication of a regulation or order, any person adversely affected by such regulations or order may file objections and request a public hearing. The implementing regulations for these statutory requirements are found at 21 CFR 12.22, which sets forth the format and instructions for filing objections and requests for a hearing. Each objection for which a hearing has been requested must be separately numbered and specify with particularity the provision of the regulation or the proposed order objected to. In addition, each objection must include a detailed description and analysis of the factual information to be presented in support of the objection as well as any report or other document relied on, with some exceptions. Failure to include this information constitutes a waiver of the right to a hearing on that objection. FDA uses the description and analysis only for the purpose of determining whether a hearing request is justified. The description and analysis do not limit the evidence that may be presented if a hearing is granted. Respondents to this information collection are those parties that may be adversely affected by an order or regulation.

In the **Federal Register** of October 25, 1999 (64 FR 57467), the agency requested comments on the proposed collections of information. No significant comments were received.

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

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
12.22	60	1	60	20	1,200

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

The burden estimate for this collection of information is based on agency data received on this administrative procedure for the past 3 years. Agency personnel responsible for processing the filing of objections and requests for a public hearing on a specific regulation or order, estimate approximately 60 requests are received by the agency annually, with each requiring approximately 20 hours of preparation time.

Dated: February 23, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–4669 Filed 2–28–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pregnancy Labeling Subcommittee of the Advisory Committee for Reproductive Health Drugs; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Pregnancy Labeling Subcommittee of the Advisory Committee for Reproductive Health Drugs.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 28, 2000, 9 a.m. to 5 p.m. and on March 29, 2000, 8 a.m. to 5 p.m.

Location: Hilton Hotel, Crystals Ballroom, 620 Perry Pkwy., Gaithersburg, MD.

Contact: Jayne E. Peterson or Robin M. Spencer, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, e-mail: petersonj@cder.fda.gov, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–44–30572 in the Washington, DC area), code 12537. Please call the Information Line for up-to-date information on this meeting.

Agenda: On March 28, 2000, the subcommittee presentations and discussions will include the following topics: (1) The status of proposed pregnancy labeling changes, (2) the status of activities related to preclinical assessment of reproductive toxicity, and (3) FDA draft guidance for industry entitled ''Establishing Pregnancy Registries'' (see 64 FR 30041, June 4, 1999, including solicitation for comments [Docket No. 99D–1541], see also the FDA Internet at www.fda.gov.cder/guidance/index.htm under the heading ''Clinical/Medical

(Draft)''). The subcommittee will also address the methodological and operational challenges in developing and running a pregnancy registry. On March 29, 2000, the subcommittee presentations and discussions will address strategies for monitoring drug risks in pregnant women.

Procedure: Interested persons may present data, information, or views, orally or in writing on issues pending before the subcommittee. Written submissions may be made to the contact person by March 14, 2000. On March 28, 2000, oral presentations from the public will be scheduled between approximately 10:15 a.m. and 10:45 a.m. and 2:45 p.m. and 3 p.m. On March 29, 2000, oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before March 14, 2000, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 18, 2000.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 00–4666 Filed 2–28–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–1127–N]

Medicare Program; Open Public Meeting on March 15, 2000 To Provide an Overview of Data Requirements for Collection of Physician and Hospital Outpatient Encounter Data From Medicare+Choice Organizations for Risk Adjustment

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces a public meeting to provide Medicare+Choice organizations, providers, practitioners, and other interested parties an overview of data requirements for physician and hospital outpatient encounter data. The meeting will address the following topics:

- Basic data requirements for physician encounter data.
- Basic data requirements for hospital outpatient encounter data.
- Update on training and customer support services.

DATES: The meeting is scheduled for March 15, 2000 from 9 a.m. until 4 p.m., e.s.t.

ADDRESSES: The meeting will be held in the HCFA Auditorium, 7500 Security Boulevard, Baltimore, Maryland, 21244–1850.

FOR FURTHER INFORMATION CONTACT: Ann Barcome, (301) 519–6700, encounterdata@aspensys.com.

SUPPLEMENTARY INFORMATION:

Background

The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) established the Medicare+Choice program. Under the BBA, HCFA must implement a risk adjustment methodology that accounts for variations in per capita costs based on health status and other demographic factors for payment to Medicare+Choice organizations (M+COs). Risk adjustment implementation must start no later than January 1, 2000.

The BBA also gives HCFA the authority to collect inpatient hospital data for discharges on or after July 1, 1997, and additional data for services occurring on or after July 1, 1998. The schedule for physician and hospital outpatient encounter data submission is as follows:

- October 1, 2000: Submission of physician data begins.
- January 1, 2001: Submission of hospital outpatient data begins with dates of services retroactive to October 1, 2000.

This notice announces a public meeting to provide an opportunity for M+COs, providers, practitioners, and other interested parties to obtain basic information on the data requirements for the collection of physician and hospital outpatient encounter data. HCFA intends to provide additional information on our data collection efforts, systems processes, training approach, and customer services. HCFA will also follow-up this meeting with intensive training in the areas of physician and hospital outpatient encounter data that will occur in June and September, respectively.

HCFA is announcing this public meeting to provide an overview of physician and hospital outpatient data and to allow for individuals and organizations familiar with issues related to physician and hospital outpatient data collection to raise questions that can be answered in subsequent training. The agenda will include short presentations by HCFA staff and Aspen Systems Corporation, the encounter data training contractor, on related topics and will conclude with a question-and-answer session.

Registration

Registration for this public meeting is required and will be on a first-come, first-serve basis, limited to two attendees per organization. A waiting list will be available for additional requests. Registration will be done via the Internet at www.hcfa.gov/events or by paper forms available at the aforementioned Internet address. A confirmation notice will be sent to attendees upon finalization of registration.

Attendees will be provided with meeting materials at the time of the meeting. We will accept written questions or requests for meeting materials either before the meeting or up to 14 days after the meeting. Written submissions must be sent to: Aspen Systems Corporation, ATTN: Ann Barcome, 2277 Research Boulvevard, Rockville, Maryland 20850. You may contact Ann Barcome at: Telephone Number: (301) 519–6700, Fax Number: (301) 519–6360, E-mail: encounterdata@aspensys.com.

(Authority: Sections 1851 through 1859 of the Social Security Act (42 U.S.C. 1395w–21 through 1395w–28))

(Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospital Insurance Program; and No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: February 18, 2000.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

[FR Doc. 00–4670 Filed 2–28–00; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries