listed in this section within one month after the meeting.

FOR FURTHER INFORMATION CONTACT: Lorrie Ballantine, (410) 786–7543 or Jennifer Carver, (410) 786–6610.

SUPPLEMENTARY INFORMATION:

I. Background

On December 21, 2000, the Congress passed the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. 106–554. Section 531(b) of BIPA mandated that we establish procedures that permit public consultation for coding and payment determinations for new DME under Medicare Part B of title XVIII of the Social Security Act (the Act). The procedures and public meetings announced in this notice are in response to the mandate of section 531(b) of BIPA.

As part of ''Operation Wheeler Dealer'', we stated in testimony before the Senate Finance Committee that we will work to make changes to the HCPCs coding for power wheelchairs that better describe the power wheelchairs currently on the market and thus assure that wheelchair payments are accurate.

We published a notice in the **Federal Register** (66 FR 58743) on November 23, 2001 with information regarding the establishment of the public meeting process for DME.

II. Registration

Registration Procedures: Registration may be completed online at *http://cms.hhs.gov/medicare/hcpcs/default.asp*, or you may contact the Power Wheelchair Public Meeting Coordinator, Lorrie Ballantine, (410) 786–7543, or Jennifer Carver, (410) 786–6610, to register by phone. The following information must be provided when registering: name, company name and address, telephone and fax numbers, e-mail address and special needs information. A CMS staff member will confirm your registration by mail, e-mail or fax.

Registration Deadline: Individuals must register by August 20, 2004.

III. Presentations and Comment Format

A. Primary Speaker Presentations

The entity that has requested to speak at the Public Meeting may designate one person to be the ''Primary Speaker'' and make a presentation at the meeting. We will post guidelines regarding the amount of time allotted to the speaker, as well as other presentation guidelines, on the official HCPCS Web site by August 27, 2004. Persons designated to be a Primary Speaker must register to attend the meeting using the registration procedures described in section II of this notice by August 20, 2004, contact the DME Public Meeting Coordinator, Lorrie Ballantine or Jennifer Carver.

At the time of registration, Primary Speakers must provide a brief, written statement regarding the nature of the information they intend to provide, and advise the meeting coordinator regarding needs for audio/visual support. In order to avoid disruption of the meeting and ensure compatibility with our systems, tapes and disk files are tested and arranged in speaker sequence well in advance of the meeting. We will accommodate tapes and disk files that are received by the DME Public Meeting Coordinator by August 27, 2004. In addition, on the day of the meeting, Primary Speakers must provide a written summary of their comments to the DME Public Meeting Coordinator.

B. Speaker Declaration

The Primary Speakers must declare, at the meeting as well as in their written summary, whether or not they have any financial involvement with the manufacturers, suppliers or competitors of power wheelchairs. This includes any payment, salary, remuneration, or benefit provided to the speaker by the manufacturer.

C. Written Comments From Meeting Attendees

We welcome written comments from persons in attendance at a public meeting, whether or not they had the opportunity to make an oral presentation. Written comments may be submitted at the meeting, or prior to the meeting via e-mail to *http://cms.hhs.gov/medicare/hcpcs/default.asp* or by regular mail to Lorrie Ballantine, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Mail Stop C5–08–27, Baltimore, MD 21244.

IV. General Information

The meetings are held in a Federal government building; therefore, Federal measures are applicable. In planning your arrival time, we recommend allowing additional time to clear security. In order to gain access to the building and grounds, participants must bring a government-issued photo identification and a copy of their confirmation of pre-registration for the meeting. Access may be denied to persons without proper identification.

Security measures also include inspection of vehicles, inside and out, at the entrance to the grounds. In addition, all persons entering the building must pass through a metal detector. All items brought to CMS, whether personal or for the purpose of demonstration or to support a presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a presentation.

Special Accommodations: Persons attending a meeting who are hearing or visually impaired and have special requirements, or a condition that requires special assistance or accommodations, must provide this information upon registering for the meeting.

Authority: Section 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 42 U.S.C. 1395hh) (Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: July 15, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 04–16527 Filed 7–22–04; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0269]

Agency Information Collection Activities; Proposed Collection; Comment Request; Radioactive Drugs for Certain Uses Research

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting requirements related to radioactive drugs used in research.

DATES: Submit written or electronic comments on the collection of information by September 21, 2004.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/*

dockets/ecomments. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Radioactive Drugs for Certain Research Uses—21 CFR 361.1 (OMB Control Number 0910–0053)—Extension

Under sections 201, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 355, and 371), FDA has the authority to issue regulations governing the use of radioactive drugs for basic informational research. Section 361.1 (21 CFR 361.1) sets forth specific regulations regarding the establishment and composition of Radioactive Drug Research Committees and their role in approving and monitoring basic research studies utilizing radiopharmaceuticals. No basic research study involving any administration of a radioactive drug to research subjects is permitted without the authorization of an FDA-approved Radioactive Drug Research Committee (§ 361.1(d)(7)). The type of research that may be undertaken with a radiopharmaceutical drug must be intended to obtain basic information and not to carry out a clinical trial. The types of basic research permitted are specified in the regulation, and include studies of metabolism, human physiology, pathophysiology, or biochemistry.

Section 361.1(c)(2) requires that each Radioactive Drug Research Committee shall select a chairman, who shall sign all applications, minutes, and reports of the committee. Each committee shall meet at least once each quarter in which research activity has been authorized or conducted. Minutes shall be kept and shall include the numerical results of votes on protocols involving use in human subjects. Under § 361.1(c)(3), each Radioactive Drug Research Committee shall submit an annual report to FDA. The annual report shall include the names and qualifications of the members of, and of any consultants used by, the Radioactive Drug Research Committee, using FDA Form 2914, and a summary of each study conducted during the proceeding year, using FDA Form 2915.

Under § 361.1(d)(5), each investigator shall obtain the proper consent required under the regulations. Each female research subject of childbearing potential must state in writing that she is not pregnant, or on the basis of a pregnancy test be confirmed as not pregnant.

Under § 361.1(d)(8), the investigator shall immediately report to the Radioactive Drug Research Committee all adverse effects associated with use of the drug, and the committee shall then report to FDA all adverse reactions probably attributed to the use of the radioactive drug.

Section 361.1(f) sets forth labeling requirements for radioactive drugs. These requirements are not in the reporting burden estimate because they are information supplied by the Federal Government to the recipient for the purposes of disclosure to the public (5 CFR 1320.3 (c)(2)).

Types of research studies not permitted under this regulation are also specified, and include those intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety and effectiveness of the drug in humans for such purposes (i.e., to carry out a clinical trial). These studies require filing of an investigational new drug application (IND) under 21 CFR 312.1, and the associated information collections are covered under OMB control number 0910–0014.

The primary purpose of this collection of information is to determine if the research studies are being conducted in accordance with required regulations. If these studies were not reviewed, human subjects could be subjected to inappropriate radiation and/or safety risks. Respondents to this information collection are the chairperson(s) of each individual Radioactive Drug Research Committee, investigators, and participants in the studies.

The source of the burden estimates was a phone survey of three chairpersons who were selected from Radioactive Drug Research Committees of different geographical areas and of varying levels of activity. These chairpersons were asked for their assessment of time expended, cost and views on completing the necessary reporting forms.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Forms	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
361.1(c)(3)	FDA 2914	80	1	80	1	80

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

21 CFR Section	Forms	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
361.1(c)(3)	FDA 2915	50	6.8	340	3.5	1190
361.1(d)(8)		50	6.8	340	0.1	34
Total						1304

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	Forms	No. of Recordkeepers	Annual Frequency per Recordkeeping	Hours per Record-Keeper	Total Hours
361.1(c)(2)		80	1 per qtr = 4 per year	10	800
361.1(d)(5)		50	6.8	0.75	38
Total					838

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

Dated: July 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–16824 Filed 7–22–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001D–0582]

Guidance for Industry on Available Therapy; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Available Therapy.'' The document is intended to provide guidance to industry on the meaning of the term ''available therapy'' as used by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

For information regarding human drug products: Janet Jones, Center for Drug Evaluation and Research (HFD–040), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5445.

For information regarding biological products: Robert Yetter, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1148, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Available Therapy.'' The term ''available therapy'' and related terms, such as ''existing treatments'' and ''existing therapy,'' appear in a number of regulations and policy statements issued by CDER and CBER, but these terms have never been formally defined by the agency. Some confusion has arisen about, for example, whether ''available therapy'' refers only to products approved by FDA for the use in question, or whether the term could also refer to products used off-label or to treatments not regulated by FDA, such as surgery. The guidance document is intended to inform the public of the agency's interpretation of the term ''available therapy.''

In the **Federal Register** of February 7, 2002 (67 FR 5831), FDA announced the availability of a draft guidance entitled ''Available Therapy.'' The document provided interested persons an opportunity to submit comments by April 8, 2002. On October 17, 2002, the United States District Court for the District of Columbia invalidated the ''Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients'' (the pediatric rule) and enjoined FDA from enforcing the rule. (See *Association of Am. Physicians and Surgeons, Inc.* v. *United States Food and Drug Admin.*, 2002 U.S. Dist. LEXIS 19689 (Oct. 17, 2002).) As a result, FDA has deleted all references to the pediatric rule in the guidance.

In addition, FDA has revised the definition of ''available therapy.'' The revised definition seeks to resolve issues raised in comments requesting clarification of the proposed definition and confusion about situations where the only available therapy has been approved under the accelerated approval regulations (21 CFR 314.500 and 601.40). The term ''available therapy'' has been revised to explain