Agenda: On July 27, 1999, the committee will discuss and make recommendations on the classification of bone dowel devices of human origin.

Procedure: On July 27, 1999, from 7:30 a.m. to 2:30 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by July 16, 1999. Oral presentations from the public regarding the classification of bone dowel devices will be scheduled between approximately 8:45 a.m. and 9:45 a.m. on July 27, 1999. Near the end of committee deliberations, a 30-minute open public session will be conducted for interested persons to address issues specific to the submission before the committee. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by July 16, 1999, 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.

Closed Committee Deliberations: On July 26, 1999, from 10:30 a.m. to 5 p.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information on a product development protocol. This portion of the meeting will be closed to permit discussion of this information (5 U.S.C. 552b(c)(4)).

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

Dated: June 22, 1999.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 99–16315 Filed 6–25–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0529]

Draft Guidance for Industry on Changes to an Approved NDA or ANDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Changes to an Approved NDA or ANDA.'' This draft guidance is intended to assist applicants in determining how they should report changes to an approved NDA or ANDA under the proposed revision to the drug regulations pertaining to supplements and other changes to an approved application published elsewhere in this issue of the **Federal Register**.

DATES: Written comments may be submitted on the draft guidance document by August 27, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm''. Submit written requests for single copies of the draft guidance for industry to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Nancy B. Sager, Center for Drug Evaluation and Research (HFD–357), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5633.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Changes to an Approved New Drug (NDA) or Abbreviated New Drug (ANDA) Application.''

On November 21, 1997, the President signed the Food and Drug Administration Modernization Act (the Modernization Act) (Pub. L. 105–115). Section 116 of the Modernization Act amended the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506A (21 U.S.C. 356a), which provides requirements for making and reporting manufacturing changes to an approved application and for distributing a drug product made with such changes. FDA is proposing to amend its regulations entitled *Supplements and other changes to an approved application* at § 314.70 (21 CFR 314.70) to conform to section 506A of the act. This proposed rule is published elsewhere in this issue of the **Federal Register**.

The purpose of this draft guidance is to provide recommendations to holders of NDA's and ANDA's who intend to make postapproval changes in accordance with section 506A of the act and the proposed amended regulations at § 314.70. This draft guidance covers recommended reporting categories for postapproval changes for drugs, other than specified biotechnology and specified synthetic biological products. Recommendations are provided for postapproval changes in: (1) Components and composition, (2) sites, (3) manufacturing process, (4) specification(s), (5) package, (6) labeling, and (7) miscellaneous changes. This guidance does not provide recommendations on the specific information that should be developed by the applicant to validate the effect of the change on the identity, strength (e.g., assay, content uniformity), quality (e.g., physical, chemical, and biological properties), purity (e.g., impurities and degradation products), or potency (e.g., biological activity, bioavailability, bioequivalence) of a product as they may relate to the safety or effectiveness of the product.

The guidance document, which cites the proposed rule for amending § 314.70, will be revised based on public comments and implemented for use as a companion document to § 314.70 when the rule is finalized. FDA welcomes comments that provide additional examples of major, moderate, and minor changes.

This draft level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). This guidance document represents the agency's current thinking on reporting categories for postapproval changes of drugs, other than specified biotechnology and specified synthetic biological products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 25, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–16190 Filed 6–25–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–222]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Independent Rural Health Center/ Freestanding Federally Qualified Health Center Cost Report and Supporting Regulations in 42 CFR, Section 413.20 and 413.24;

Form No.: HCFA–222;

Use: The independent rural health clinic/freestanding federally qualified health center (RHC/FQHC) cost report is the cost report to be used by the mentioned clinics/centers to submit annual information to achieve a settlement of costs for health care services rendered to Medicare beneficiaries. This form is used to collect the pertinent information from the RHC's and FQHC's in order to determine their Medicare cost reimbursement;

Frequency: Annually;

Affected Public: Not-for-profit institutions, State, local or tribal government, and business or other for-profit;

Number of Respondents: 3,000;

Total Annual Responses: 3,000;

Total Annual Hours Requested: 150,000.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: June 21, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–16395 Filed 6–25–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier HCFA–R–286]

Emergency Clearance: Public Information Collection Requirements Submitted to the Office of Management and Budget (OMB)

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services (DHHS), is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity of the utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

We are, however, requesting an emergency review of the information collection referenced below. In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, we have submitted to the Office of Management and Budget (OMB) the following requirements for emergency review. The fact that this collection of this information is needed before the expiration of the normal time limits under OMB's regulations at 5 CFR, Part 1320, will cause public harm. We are requesting an emergency review.

If HCFA cannot disseminate information in a timely manner to partners who work with Medicare beneficiaries, as benefits counselors, the beneficiaries will not be able to make informed choices. The present request is for OMB authorization to collect data on the reactions of users of the web site, www.medicare.gov/nmep. We will use the data to improve the web site so that it can best serve the needs of the users. The designers of the web site are preparing new sections, functionality, and updates and will introduce changes to the site by the end of July 1999. Expedited review of this submission is requested so that pending enhancements and updates incorporate information collected from users. With an expedited review, the staff of the web site will have evaluation findings in sufficient time to guide the revisions planned for the site. In addition to the need for having feedback to implement anticipated changes in the web site, the World Wide Web site was created through Federal law and requires a systematic assessment. Under the 1997 Balanced Budget Act, a provision was established to provide information to beneficiaries in order to promote informed choice. One activity for widely disseminating information on coverage options, that was required, was the creation of ''an Internet site through which individuals may electronically obtain information on such options and Medicare+ Choice (MEDICARE+CHOICE) plans in states which MEDICARE+CHOICE plans are offered.'' As a result, the medicare.gov/nmep site was created to provide Medicare beneficiaries, their caregivers, and partners with an official source for Medicare information on the Internet. This site, medicare.gov, was designed for partners in the national Alliance network and for others interested in providing and disseminating up-to-date