individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the guidance document and received comments are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

A copy of the guidance document may be obtained through FDA's Internet site at http://www.fda.gov/cber/guidelines.htm.

Dated: November 16, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–30526 Filed 11–22–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0529]

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 guidance for industry entitled ''Changes to an Approved NDA or ANDA.'' This guidance is intended to assist applicants in determining how they should report changes to an approved new drug application (NDA) or abbreviated new drug application (ANDA).

DATES: Written comments may be submitted at any time.

ADDRESSES: Copies of this guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of this 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 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; e-mail: pac314__70@cder.fda.gov, for questions about content of the guidance.

SUPPLEMENTARY INFORMATION: On November 21, 1997, the President signed the Food and Drug Administration Modernization Act (the Modernization Act) (Public Law 105–115). Section 116 of the Modernization Act amended the 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 announcing the availability of a guidance for industry entitled ''Changes to an Approved NDA or ANDA Application.'' The purpose of this 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. This 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) manufacturing sites, (3) manufacturing process, (4) specifications, (5) package, (6) labeling, (7) miscellaneous changes, and (8) multiple related changes. This guidance does not provide recommendations on the specific information that should be developed by the applicant to assess 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, and bioequivalence) of a product as they may relate to the safety or effectiveness of the product.

In the **Federal Register** of June 28, 1999 (64 FR 34660), FDA announced the availability of a draft version of this guidance and gave interested persons an opportunity to submit comments through August 27, 1999. All comments received during the comment period have been carefully reviewed and incorporated in this revised guidance, where appropriate.

The agency received multiple comments on three specific issues. First, some comments objected to the agency's proposal to include as an example of an annual report change ''Any change made to comply with an official compendium that is consistent with FDA requirements and that provides the same or greater level of assurance of the identity, strength, quality, purity, or potency of the material being tested as the analytical procedure described in the approved application.'' The agency has revised this example as recommended in the comments to state ''Any change made to comply with an official compendium.'' Second, the agency has removed from the guidance the recommendation ''list all changes included in the supplement or annual report in the cover letter.'' These issues, however, are still under consideration with regard to FDA's proposal to amend its regulations entitled *Supplements and other changes to an approved application* at § 314.70 (21 CFR 314.70), which published in the **Federal Register** of June 28, 1999 (64 FR 34608). If necessary, FDA will revise this guidance to make it consistent with the final rule for § 314.70.

Third, the agency received comments requesting that the phrase ''change that may affect sterility assurance,'' which is used throughout the guidance, be revised to, for example, ''change that may significantly affect sterility assurance'' or ''change that may adversely affect sterility assurance.'' FDA did not revise the guidance as suggested because the phrase as proposed in the guidance is consistent with the phrasing used in existing regulations (e.g., 21 CFR 601.12(b)(2)(vi)). If during the review of the comments on the proposed rule to amend § 314.70 FDA decides to revise this phrasing, this guidance will be revised to make it consistent with the final rule for § 314.70.

This guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on how it will apply the requirements of section 506A of the act for NDA and ANDA 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 requirements of the applicable statute, regulations, or both.

FDA has established an e-mail address where an applicant can send questions about the content of the guidance, such as requesting clarification of information in the guidance or requesting guidance on the reporting category of particular change it wants to implement. The e-mail address is: pac314__70@cder.fda.gov.

This guidance document contains collections of information that require clearance by the Office of Management

and Budget (OMB) under the Paperwork Reduction Act of 1995. In a notice published in the **Federal Register** (64 FR 59776; November 3, 1999), FDA announced that this collection of information has been submitted to OMB for emergency processing. This notice also solicited comments on the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless a currently valid OMB control number has been displayed.

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments on the guidance. 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 guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 16, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–30481 Filed 11–18–99; 1:55 pm]

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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 of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments Are Invited On

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: The Impact of the State Child Health Insurance Program on Selected Community Health Centers and Maternal Health Programs: NEW

This study proposes to determine the impact of SCHIP implementation on the insurance status of children served by two HRSA programs—community health centers (CHCs) and health departments' maternal and child health (MCH) programs—as well as the impact of SCHIP on these grantee organizations.

Transactional data will be reviewed in up to 21 HRSA grantee organizations from seven states and will extract encounter-level administrative data (encrypted individual code, date of birth, gender, dates of service, CPT–4 codes, and insurance status) at time of each service for 1997, 1998, and 1999.

Up to 20 former CHC or MCH patients (or their parents or guardians in the case of minors) will be surveyed by phone or mail in each site.

These will be patients for whom retrospective data are available but who are no longer active users of the HRSA grantees.

The estimated response burden is as follows:

TRANSACTIONAL DATA EXTRACTION

Type of respondent	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden
Community Health Centers or Maternal and Child Health Program	21	2	42	5	210
Telephone/Mail Interviews/Surveys					
Former Users	420	1	420	.50	210
Total	441		462		420

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: November 16, 1999.

Jane Harrison,

Director, Division of Policy Review and Coordination.

[FR Doc. 99–30528 Filed 11–22–99; 8:45 am]

BILLING CODE 4160–15–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4541–N–03]

Notice of Proposed Information Collection: Comment Request Fair Housing Assistance Program SuperNOFA Application Kit

AGENCY: Office of the Assistant Secretary for Fair Housing and Equal Opportunity, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement concerning the *Fair Housing Assistance Program* (FHAP) will be submitted to the Office of Management and Budget (OMB) for review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: Comments due date: January 24, 2000.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Lauretta Dixon, Department of Housing