

all amendments and supplements thereto on the ground that the applicants have failed to submit the reports required under § 314.81.

In accordance with section 505 of the act and part 314 (21 CFR part 314), the applicants are hereby provided an opportunity for a hearing to show why the applications listed above should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these applications.

An applicant who decides to seek a hearing shall file: (1) On or before April 11, 1996, a written notice of participation and request for a hearing, and (2) on or before May 13, 1996, the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation, and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing, are contained in § 314.200 and in 21 CFR part 12.

The failure of an applicant to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that applicant not to avail itself of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the applications and the drug products may not thereafter lawfully be marketed, and FDA will begin appropriate regulatory action to remove the products from the market. Any new drug product marketed without an approved new drug application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. Reports submitted to remedy the deficiencies must be complete in all respects in accordance with § 314.81. If the submission is not complete or if a request for hearing is not made in the required format or with the required reports, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions pursuant to this notice of opportunity for a hearing are to be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 505 (21 U.S.C. 355)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: February 28, 1996.
Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 96-5748 Filed 3-11-96; 8:45 am]

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Health Care Financing Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

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 collection for public comment. Interested persons are invited to send comments regarding the 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:* Payment Adjustment for Sole Community Hospitals; *Form No.:* HCFA-R-79; *Use:* Hospitals designated as "Sole Community Hospitals" that experience a five percent decrease in discharges in one cost reporting period, as compared to the previous period, due to unusual circumstances, beyond its control, may request an adjustment to its Medicare payment amount. *Frequency:* On

occasion; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and State, local or tribal government; *Number of Respondents:* 40; *Total Annual Responses:* 40; *Total Annual Hours Requested:* 160.

To request copies of the proposed paperwork collections referenced above, call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections should be sent within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address:

HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: Louis Blank, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: March 4, 1996.

Kathleen B. Larson,

Director, Management Planning and Analysis Staff, Office of Financial and Human Resources.

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Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes abstracts of information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129. The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Ryan White Comprehensive AIDS Resources Emergency Act of 1990, Title IV—The Maternal and Child Health Bureau (MCHB) proposes to collect aggregated data from 38 grantees and their 72 local service providers that are funded under Section 2671 of the Public Health Service Act (42 U.S.C. 300ff-71). Data will be collected from grantees and providers on the organizational structures, service delivery approaches, numbers and demographic characteristics of clients served, service utilization, and activities related to outreach, prevention, and education. The data collection strategy includes six tables that the grantees and their local