III. Notice of Opportunity for a Hearing

On the basis of all the data and information available to her, the Director of the Center for Drug Evaluation and Research is unaware of any adequate and well-controlled clinical investigation, conducted by experts who are qualified by scientific training and experience, meeting the requirements of section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355), 21 CFR 314.126, and 21 CFR part 320 that demonstrates effectiveness (i.e., bioavailability/bioequivalence) of the drugs listed in section II of this document and that is in compliance with the conditions established in the September 7, 1984, and December 26, 1985, notices for continued marketing.

Therefore, notice is given to the holders of the NDA's and ANDA's listed in section II of this document and to all other interested persons that the Director of the Center for Drug Evaluation and Research proposes to issue an order under section 505(e) of the act withdrawing approval of the applications and all amendments and supplements thereto on the ground that new information before her with respect to the drug products, evaluated together with the evidence available to her when the applications were approved, shows there is a lack of substantial evidence that the drug products will have the effect they purport or are represented to have under the conditions of use prescribed, recommended, or suggested in the labeling.

In addition to the holders of the applications specifically named previously, this notice of opportunity for hearing applies to all persons who manufacture or distribute a drug product, not the subject of an approved application, that is identical, related, or similar to a drug product named in section II of this document, as defined in § 310.6. It is the responsibility of every drug manufacturer or distributor to review this notice of opportunity for hearing to determine whether it covers any drug product that they manufacture or distribute. Such manufacturers or distributors may request an opinion of the applicability of this notice to a specific drug product by writing to the Division of Prescription Drug Compliance and Surveillance (address above).

This notice of opportunity for a hearing encompasses all issues relating to the legal status of the drug products subject to it (including identical, related, or similar drug products as defined in § 310.6), e.g., any contention that any such product is not a new drug because it is generally recognized as safe and effective within the meaning of section 201(p) of the act (21 U.S.C. 3241(p)) or because it is exempt from part or all of the new drug provisions of the act under the exemption for products marketed before June 25, 1938, in section 201(p) of the act, or under section 107(c) of the Drug Amendments of 1962, or for any other reason.

In accordance with section 505 of the act and the regulations issued under it (parts 310 and 314 (21 CFR parts 310 and 314)), an applicant and all other persons subject to this notice are hereby given an opportunity for hearing to show why approval of the applications should not be withdrawn.

An applicant or any other person subject to this notice who decides to seek a hearing shall file: (1) On or before May 20, 1999, a written notice of appearance and request for hearing, and (2) on or before June 21, 1999, the data, information, and analyses relied on to demonstrate that there is a genuine issue of material fact to justify a hearing, as specified in § 314.200. Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, a notice of appearance 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 §§ 314.150, 314.151, and 314.200 and in 21 CFR part 12.

The failure of an applicant or any other person subject to this notice to file a timely written notice of appearance and request for hearing, as required by § 314.200, constitutes an election by that person not to use the opportunity for a hearing concerning the action proposed and a waiver of any contentions concerning the legal status of that person's drug product(s). 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. If it conclusively appears from the face of the data, information, and factual analyses in the request for hearing that there is no genuine and substantial issue of fact which precludes the withdrawal of approval of the application, or when a request for hearing is not made in the required format or with the required analyses, the Commissioner of Food and Drugs will enter summary judgment against the person(s) who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing are to be filed in four copies. Except for data and information prohibited from public disclosure under section 301 of the act (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 section 505 of the act and under authority delegated to the Director of the Center for Drug Evaluation and Research (21 CFR 5.82).

Dated: April 13, 1999.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 99–9770 Filed 4–19–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–R–70]

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 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: Information Collection Requirements in HSQ–110, Acquisition, Protection and Disclosure of Peer Review Organization Information and Supporting Regulations in 42 CFR, 476.104, 476.105, 476.116, and 476.134;

Form No.: HCFA–R–70 (OMB# 0938–0426);

Use: ''Medicare Disclosure Information, Regulatory'' The Peer Review Improvement Act of 1982 authorizes PRO's to acquire information necessary to fulfill their duties and functions and places limits on disclosure of the information. These requirements are on the PRO to provide notices to the affected parties when disclosing information about them. These requirements serve to protect the rights of the affected parties;

Frequency: On occasion;

Affected Public: Business or other for-profit, Individuals or Households, and Not-for-profit institutions;

Number of Respondents: 53;

Total Annual Responses: 53;

Total Annual Hours: 30,789.

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: April 12, 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. 99–9804 Filed 4–19–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[HCFA–2029–FN]

RIN 0938–AJ42

Medicare Program; Recognition of the Community Health Accreditation Program, Inc. (CHAP) for Hospices

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

ACTION: Final notice.

SUMMARY: This notice recognizes the Community Health Accreditation Program, Inc. (CHAP) as a national accreditation organization for hospices that request participation in the Medicare program. We believe that accreditation of hospices by CHAP demonstrates that all Medicare hospice conditions of participation are met or exceeded. Thus, we grant deemed status to those hospices accredited by CHAP. The proposed notice included the application from the Joint Commission for Accreditation of Healthcare Organizations (JCAHO). We have separated the final notices to appropriately process each application and will issue a separate final notice containing the decision for JCAHO under HCFA–2039–FN.

EFFECTIVE DATE: This final notice is effective April 20, 1999 through November 20, 2003.

FOR FURTHER INFORMATION CONTACT: Joan C. Berry, (410) 786–7233.

SUPPLEMENTARY INFORMATION:

I. Background

A. Laws and Regulations

Under the Medicare program, eligible beneficiaries may receive covered palliative services in a hospice provided certain requirements are met. The regulations specifying the Medicare conditions of participation for hospice care are located in 42 CFR part 418. These conditions implement section 1861(dd) of the Social Security Act (the Act), which specifies services covered as hospice care and the conditions that a hospice program must meet in order to participate in the Medicare program.

Generally, in order to enter into an agreement with Medicare, a hospice must first be certified by a State survey agency as complying with the conditions or standards set forth in part 418 of the regulations. Then, the hospice is subject to routine surveys by a State survey agency to determine whether it continues to meet Medicare requirements. There is an alternative, however, to surveys by State agencies.

Current section 1865(b)(1) of the Act permits ''accredited'' hospices to be exempt from routine surveys by State survey agencies to determine compliance with Medicare conditions of participation. Accreditation by an accreditation organization is voluntary and is not required for Medicare certification. Section 1865(b)(1) of the Act provides that, if a provider is accredited by a national accreditation body that has standards that meet or exceed the Medicare conditions, the Secretary can ''deem'' that hospice as having met the Medicare requirements.

We have rules at part 488 that set forth the procedure we use to review applications submitted by national accreditation organizations requesting our approval. A national accreditation organization applying for approval must furnish to us information and materials listed in the regulations at § 488.4. The regulations at § 488.8 (''Federal review of accreditation organizations'') detail the Federal review and approval process of applications for recognition as an accrediting organization. On April 26, 1996, however, new legislation entitled ''Omnibus Consolidated Rescissions and Appropriations Act of 1996'' (Pub. L. 104–134) was enacted.

Section 1865(b)(3)(A) of the Act, as amended by section 516 of Pub. L. 104–134, requires us to publish a notice in the **Federal Register** within 60 days after receiving an accreditation organization's written request that we make a determination regarding whether its accreditation requirements meet or exceed Medicare requirements. Section 1865(b)(3)(A) of the Act also requires that we identify in the notice the organization and the nature of the request and allow a 30-day comment period. This section further requires that we publish a notice of our approval or disapproval within 210 days after we receive a complete package of information and the organization's application.

B. Proposed Notice

On September 11, 1998, we published a proposed notice (63 FR 48735) announcing the requests of CHAP and JCAHO for our approval as national accreditation organizations for hospices. In the notice, we detailed the factors on which we would base our evaluation. (We inadvertently gave the citation for the regulations governing our evaluation as § 488.8, ''Federal review of accreditation organizations,'' rather than as § 488.4, ''Application and reapplication procedures for accreditation organizations.'') Under section 1865(b)(2) of the Act and our regulations at § 488.4, our review and evaluation of the CHAP application were conducted in accordance with the following factors:

- A determination that CHAP is a national accreditation body, as required by the Act.
- A determination of the equivalency of CHAP's requirements for a hospice to our comparable hospice requirements.
- A review of CHAP's survey processes to determine the following:

—The comparability of CHAP's processes to those of State agencies, including survey frequency; its ability to investigate and respond