206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3032.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 1M4727) has been filed by the National Fisheries Institute, 1901 North Fort Myer Dr., Arlington, VA 22209. The petition proposes to amend the food additive regulations in Part 179 *Irradiation in the Production, Processing and Handling of Food* (21 CFR part 179) to provide for the safe use of ionizing radiation for control of foodborne pathogens in raw-, frozen-, cooked-, partially cooked-, shelled-, or dried-crustaceans, or cooked- or ready-to-cook crustaceans processed with batter, breading, spices, or small amounts of other food ingredients.

The agency has determined under 21 CFR 25.32(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: January 11, 2001.

Alan M. Rulis,

Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 01–3095 Filed 2–5–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1672]

Ashford Blood Bank, Inc.; Opportunity for Hearing on a Proposal to Revoke U.S. License No. 0740–001

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for a hearing on a proposal to revoke the establishment license (U.S. License No. 0740–001) and product licenses issued to Ashford Blood Bank, Inc., for the manufacture of Whole Blood and Red Blood Cells. The proposed revocation is based on the fact that authorized FDA employees have been unable to gain access to either of the establishment's locations for the purpose of carrying out a required inspection of the facility and that the manufacturing of products has been discontinued to an extent that a meaningful inspection or evaluation cannot be made.

DATES: The firm may submit written requests for a hearing by March 8, 2001, and any data and information justifying a hearing by April 9, 2001. Other interested persons may submit written comments on the proposed revocation by April 9, 2001.

ADDRESSES: Submit written requests for a hearing, any data and information justifying a hearing, and any written comments on the proposed revocation to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Joseph L. Okrasinski, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA is initiating proceedings to revoke the establishment license (U.S. License No. 0740–001) and product licenses issued to Ashford Blood Bank, Inc., Ashford Medical Center, suite 401–402, Santurce, PR 00907, for the manufacture of Whole Blood and Red Blood Cells. Proceedings to revoke the licenses are being initiated because: (1) Authorized FDA employees have been unable to gain access to either of the establishment's locations for the purpose of carrying out a required inspection of the facility, and (2) manufacturing of products has been discontinued to an extent that a meaningful inspection or evaluation cannot be made.

In a certified return-receipt letter dated October 28, 1997, FDA notified an authorized official of the firm that FDA had suspended the firm's establishment and product licenses for the manufacture of Whole Blood and Red Blood Cells at its facilities at Santurce, PR, and Bayamon, PR. This action was based on the fact that significant deviations from the regulations were noted by FDA's San Juan district office during inspections of the facilities conducted August 19, 1997, through September 17, 1997, and September 9, 1997, through September 17, 1997, respectively. FDA's San Juan district office attempted to conduct additional inspections of the two Ashford facilities. On May 1, 1998, FDA investigators attempted to inspect the satellite collection facility at Bayamon, PR, but found that the facility was no longer in operation, and the manufacturing of Whole Blood and Red Blood Cells had been discontinued. On November 23, 1999, FDA investigators attempted to inspect the main facility in Santurce, PR, but found that the facility was no longer in operation and the manufacturing of Whole Blood and Red Blood Cells had been discontinued.

In certified, return-receipt letters dated April 13, 2000, sent to the firm's facility at Santurce, PR, and also to the Ashford Blood Bank, Inc., P.O. Box 195034, San Juan, PR, 00919, FDA notified an authorized official of the firm that FDA's attempts to conduct inspections of the two facilities at Santurce, PR and Bayamon, PR were unsuccessful because the facilities were no longer in operation and the manufacture of Whole Blood and Red Blood Cells had been discontinued. The letter also advised the authorized official that, under 21 CFR 601.5(b)(1) and (b)(2) (now codified as 21 CFR 601.5(b)(1)(i) and (b)(1)(ii)), when FDA finds that authorized employees have been unable to gain access to an establishment for the purpose of carrying out an inspection under 21 CFR 600.21, or the manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection cannot be made, the Commissioner of Food and Drugs (the Commissioner) shall institute proceedings for license revocation. In the same letter, FDA stated that a meaningful inspection could not be made at the establishment and notified the firm of FDA's intent to revoke U.S. License No. 0740–001 and its intent to offer an opportunity for a hearing.

Because FDA has made reasonable efforts to notify the firm of the proposed revocation and has not received any response from the firm to the revocation letter, FDA is proceeding under 21 CFR 12.21(b) and publishing this notice of opportunity for a hearing on a proposal to revoke the licenses of the previously mentioned firm.

FDA has placed copies of the documents relevant to the proposed revocation on file with the Dockets Management Branch (address above) under the docket number found in brackets in the heading of this notice. These documents include: (1) Summary of Findings, May 1, 1998; (2) memorandum regarding FDA visit to Santurce location, November 23, 1999; and (3) FDA letters to the authorized official dated October 28, 1997, and April 13, 2000. These documents are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Ashford Blood Bank, Inc., may submit a written request for a hearing to the Dockets Management Branch by March

8, 2001, and any data and information justifying a hearing must be submitted by April 9, 2001. Other interested persons may submit written comments on the proposed license revocation to the Dockets Management Branch by April 9, 2001. The failure of the licensee to file a timely written request for a hearing constitutes an election by the licensee not to avail itself of the opportunity for a hearing concerning the proposed license revocation.

FDA's procedures and requirements governing a notice of opportunity for a hearing, notice of appearance and request for a hearing, grant or denial of a hearing, and submission of data to justify a hearing on proposed revocation of a license are contained in 21 CFR parts 12 and 601. A request for a hearing may not rest upon mere allegations or denials but must set forth a genuine and substantial issue of fact. If the Commissioner determines upon review of any objections or requests for a hearing that a hearing is not justified, in whole or in part, or if a request for a hearing is not made within the required time with the required format or required analyses, the Commissioner will deny the hearing request, with an explanation for the denial.

Two copies of any submissions are to be provided to FDA, except that individuals may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document. Such submissions, except for data and information prohibited from public disclosure under 21 CFR 10.20(j)(2)(i), 21 U.S.C. 331(j), or 18 U.S.C. 1905, may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under section 351 of the Public Health Service Act (42 U.S.C. 262) and sections 201, 501, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 355, and 371), and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director of the Center for Biologics Evaluation and Research (21 CFR 5.67).

Dated: January 24, 2001.

Kathryn C. Zoon,

Director, Center for Biologics Evaluation and Research.

[FR Doc. 01–3094 Filed 2–5–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

Notice of Hearing: Reconsideration of Disapproval of Missouri State Plan Amendment (SPA) 99–29

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

ACTION: Notice of hearing.

SUMMARY: This notice announces an administrative hearing on March 8, 2001, at 10:00 a.m., Plaza Room 664, Richard Bolling Federal Building, 601 E. Twelfth Street, Kansas City, Missouri 64106, to reconsider our decision to disapprove Missouri SPA 99–29.

CLOSING DATE: Requests to participate in the hearing as a party must be received by the presiding officer by February 21, 2001.

FOR FURTHER INFORMATION CONTACT: Kathleen Scully-Hayes, Presiding Officer, HCFA, C1–09–13, 7500 Security Boulevard, Baltimore, MD 21244, Telephone: (410) 786–2055.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider HCFA's decision to disapprove Missouri's SPA 99–29. Missouri submitted SPA 99–29 on December 29, 1999, which proposed to pay for school-based assessment services described in an individualized education plan pursuant to the Individuals with Disabilities Education Act (IDEA) using a bundled rate methodology. One rate would be paid for a variable package of assessment services, regardless of the number of assessment services provided to a particular child. As explained below, HCFA disapproved Missouri SPA 99–29 after consulting with the Secretary on October 31, 2000.

Section 1116 of the Social Security Act (the Act) and 42 CFR part 430, establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a State plan or plan amendment. HCFA is required to publish a copy of the notice to a State Medicaid agency that informs said agency of the time and place of the hearing and the issues to be considered. If the agency is subsequently notified of additional issues that will be considered at the hearing, that notice will also be published.

In accordance with the requirements contained at 42 CFR 430.76(b)(2), any individual or group that wants to participate in the hearing as a party must petition the presiding officer within 15 days after publication of this notice. Any interested person or organization that wants to participate as amicus curiae must petition the presiding officer before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c). If the hearing is later rescheduled, the presiding officer will notify all participants.

The first issue is whether payment for Medicaid services using a bundled rate methodology, under which payment is made at a single rate for one or more in a group of different services furnished to an eligible individual over a fixed period of time, meets the conditions set forth in section 1902(a)(30) of the Act. Section 1902(a)(30)(A) provides that Medicaid State plans must provide for such methods and procedures relating to the payment for care and services available under the plan as may be necessary to ensure that payments are consistent with efficiency, economy, and quality of care. The amendment proposed to pay for school-based assessment services furnished pursuant to the IDEA using a bundled rate methodology. Under the proposed payment methodology, one rate would be paid for a variable package of assessment services, regardless of the number of assessment services provided to a particular child. As explained below, HCFA was unable to approve Missouri SPA 99–29 because the proposed payment methodology was not in compliance with section 1902(a)(30)(A) of the statute, and could not generate sufficient documentation to establish such compliance.

On May 21, 1999, HCFA issued a letter to all State Medicaid directors indicating that it would no longer approve State plan amendments proposing reimbursement for school-based health services using a bundled rate. That letter described a bundled rate as a single rate for one or more in a group of different services furnished to an eligible individual during a fixed period of time. In the May 21 letter, HCFA explained that such rates do not ensure accurate and reasonable payments consistent with efficiency, economy, and quality of care. Specifically, HCFA stated that the bundled rate is inconsistent with economy since the rate is not designed to accurately reflect true costs or reasonable fee-for-service rates. The bundled rate is also inconsistent with efficiency since it requires substantially more Federal oversight resources to establish the accuracy and reasonableness of State expenditures. In sum, HCFA concluded that, with a bundled rate, there is no reliable basis for determining that the payments