

engineers/technicians within the holding agency must determine if the biomedical equipment is:

- (1) Y2K compliant;
- (2) Y2K noncompliant; or
- (3) Y2K status unknown.

c. *How do we dispose of biomedical equipment if it is Y2K compliant?* If Y2K compliant, excess biomedical equipment must be identified as "Y2K compliant" on the equipment itself and on the reporting document (SF 120) and disposed of through normal disposal procedures described in FPMR 101-43.3, 101-44.2 and 101-45.3. Executive agencies obtaining excess Y2K compliant biomedical equipment must reflect the "Y2K compliant" status on all inventory control documentation pertaining to such equipment.

d. *How do we dispose of biomedical equipment that is not Y2K compliant?* If Y2K status of biomedical equipment is noncompliant, the holding agency must determine whether the equipment can be economically repaired (refer to FDA's critical item list at <http://www.fda.gov/cdrh/yr2000/year2000.html>) or whether it must be destroyed in accordance with FPMR 101-45.9. Destruction means rendering the equipment completely inoperable for its intended use. For items that can be economically repaired, the recipient should bear the cost for remediation and testing. In no case should excess or surplus Y2K noncompliant biomedical equipment be transferred for use without the assurance that Y2K remediation and testing will be performed. Otherwise, the equipment will be destroyed.

e. *What do we do with biomedical equipment when the Y2K status cannot be determined?* Excess biomedical equipment that is Y2K status unknown may not be transferred. If the Y2K status cannot be economically determined by the holding agency, it should be destroyed in accordance with FPMR 101-45.9 and 101-42.403(e).

#### 6. *IT equipment.*

a. *Do we also report the status of IT equipment?* Yes, all IT equipment must also be identified by the holding agency as Y2K compliant, Y2K noncompliant, or Y2K status unknown. The Y2K status must be visible on the equipment and all reporting documents.

b. *What are the disposal procedures for IT equipment?* IT equipment will be disposed of through normal disposal procedures as described in FPMR 101-43.3, 101-44.2 and 101-45.3.

7. *Who should we contact for further information?* Martha Caswell, Personal Property Management Policy Division, Office of Governmentwide Policy, General Services Administration, Washington, DC 20405; telephone (202)

501-3846; e-mail [martha.caswell@gsa.gov](mailto:martha.caswell@gsa.gov).

Dated: August 4, 1999.

**Stanley C. Langfeld,**

*Acting Associate Administrator, Office of Governmentwide Policy.*

[FR Doc. 99-20562 Filed 8-9-99; 8:45 am]

BILLING CODE 6820-24-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 96F-0493]

#### Gerard T. O'Brien; Denial, Response to Objections

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; order denying objection.

**SUMMARY:** The Food and Drug Administration (FDA) is denying an objection to the agency's denial of a petition (FAP 7A4530) proposing that the food additive regulations be amended to provide for the safe use of a mixture of hydrogen peroxide and sodium bicarbonate as an antimicrobial agent on fresh poultry. The objector did not request a hearing, and thus waives the right to such a hearing.

#### FOR FURTHER INFORMATION CONTACT:

James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204-0001, 202-418-3078.

**SUPPLEMENTARY INFORMATION:** In a notice published in the **Federal Register** of January 2, 1997 (62 FR 101), FDA announced that a food additive petition (FAP 7A4530) had been filed by Gerard T. O'Brien, 2162 Skyline Dr., Gainesville, GA 30501. The petitioner requested that FDA amend the food additive regulations to provide for the safe use of a mixture of hydrogen peroxide and sodium bicarbonate as an antimicrobial agent on fresh poultry. In the **Federal Register** of September 26, 1997 (62 FR 50617), FDA published an order denying this petition, in accordance with § 171.100(a) (21 CFR 171.100(a)), because FDA concluded that the petition did not contain sufficient data and information to allow the agency to determine either that the food additive is safe for its proposed use or that the additive will have its intended technical effect.

In its denial, the agency explained that the petitioner had failed to provide data and information to demonstrate that the hydrogen peroxide and sodium bicarbonate mixture would significantly

reduce pathogenic bacterial contamination on the surface of fresh poultry, e.g., *Salmonella*, *Escherichia coli*, and psychrophiles, and that the petitioner had failed to provide data and information on whether oxidative effects of hydrogen peroxide would occur on poultry as a result of the proposed use. FDA noted that the agency had requested certain data from the petitioner on several occasions during its review of the petition, including laboratory data to demonstrate that there is reduced bacterial contamination on poultry processed with hydrogen peroxide and sodium bicarbonate, TBA (2-thiobarbituric acid) values (an indicator of oxidation) in skin/fat and meat from processed poultry, and a basis to estimate the amount of hydrogen peroxide that reacts with poultry during the proposed treatment. Because the petitioner failed to provide these data and information, FDA did not have a sufficient basis to determine whether the food additive would achieve its intended technical effect or was safe for the intended use. Accordingly, FDA denied the petition.

Under § 171.110 of the food additive regulations, objections and requests for a hearing are governed by part 12 (21 CFR part 12) of FDA's regulations. Section 12.22(a) sets forth the conditions that each objection must meet for filing. Section 12.22(a) provides that each objection must: (1) Be submitted on or before the 30th day after the date of publication of the final rule; (2) be separately numbered; (3) specify with particularity the provision of the order objected to; (4) state whether a hearing is requested; and (5) for each objection for which a hearing is requested, include a detailed description of the factual information to be presented in support of the objection. Failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection.

In response to the agency's denial of FAP 7A4530, the petitioner, on October 22, 1997, submitted material within the 30-day objection period challenging the denial. The petitioner submitted, as its objection, references to three complaints filed in various legal proceedings in Federal court. Such complaints were filed before the date of the agency's denial of the petition, and therefore, were not written in response to the agency's denial, but were submitted as "objections." A copy of one of the referenced complaints, filed on August 25, 1997, in the U.S. District Court for the Northern District of Georgia, was included in the submission. In addition,

the petitioner submitted a copy of the agency's September 26, 1997, order that had been annotated (apparently by the petitioner) with words and statements that asserted that FDA's findings were wrong. The petitioner provided no explanation for its assertions.

FDA has reviewed the material submitted by the petitioner. The submitted material is not in the form that is required for the filing of objections under § 12.22(a). Although the petitioner submitted material that he characterized as "objections," he failed to identify the specific provisions of the agency's order to which he objected. Further, the petitioner did not request a hearing for any "objection" and therefore, waived the right to a hearing under § 12.22(a)(4). Even if the agency assumed that the petitioner, in his submission, made an implicit request for a hearing, the petitioner did not provide a detailed description and analysis of the factual information to be presented in support of each of his objections, as required under § 12.22(a)(5). Therefore, the material submitted did not meet the conditions for filing objections under § 12.22(a).

Moreover, even if the petitioner's submission is assumed to be an objection that meets the requirements of filing and contains an implicit request for a hearing, the petitioner has not met the requirements for the grant of a request for a hearing under § 12.24(b). Specifically, the petitioner has not identified any genuine and substantial issue of fact for resolution at a hearing (§ 12.24(b)(1)). The petitioner has not provided a factual basis for why the data and information that FDA requested, but that were not provided in the petition, are not necessary in order for the agency to determine whether the proposed use of the food additive is safe, or to determine that the proposed use of the additive will achieve its intended technical effect. The petitioner merely asserted that the agency's determination was wrong, but failed to provide a basis for this assertion. Furthermore, because the petitioner did not provide a detailed description and analysis of the specific factual information intended to be presented in support of any objection, the agency will not use its discretion under § 12.30(b) to order a hearing.

In summary, the petitioner alleges no misapplication of the law by FDA in the agency's order of denial. Moreover, the petitioner has provided the agency with no genuine or substantial issue of fact that could form the basis for FDA to reconsider its decision denying FAP 7A4530. Furthermore, the petitioner's submission provides no basis for granting a hearing because no such

request was made, and even if such a request is implied, the petitioner did not include specifically identified reliable evidence that could lead to resolution of any factual issue in dispute. A hearing will not be granted on the basis of mere allegations or denials, or general descriptions of positions and contentions (§ 12.24(b)(2)). Therefore, in accordance with §§ 12.28 and 12.30(b), FDA is denying in its entirety the petitioner's objection to the agency's order denying FAP 7A4530.

Dated: August 3, 1999.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 99-20487 Filed 8-9-99; 8:45 am]

BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of Refugee Resettlement

#### Refugee Resettlement Program: Final Notice of Availability of Formula Allocation Funding for FY 1999 Targeted Assistance Grants for Services to Refugees in Local Areas of High Need

**AGENCY:** Office of Refugee Resettlement (ORR), ACF, DHHS.

**ACTION:** Final notice of availability of formula allocation funding for FY 1999 targeted assistance grants to States for services to refugees<sup>1</sup> in local areas of high need.

**SUMMARY:** ORR announces the availability of funds and award procedures for FY 1999 targeted assistance grants for services to refugees under the Refugee Resettlement Program (RRP). These grants are for service provision in localities with large refugee populations, high refugee concentrations, and high use of public assistance, and where specific needs exist for supplementation of currently

<sup>1</sup> In addition to persons who meet all requirements of 45 CFR 400.43, "Requirements for documentation of refugee status," eligibility for targeted assistance includes (1) Cuban and Haitian entrants, under section 501 of the Refugee Education Assistance Act of 1980 (Pub. L. 96-422); (2) certain Amerasians from Vietnam who are admitted to the U.S. as immigrants under section 584 of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1988, as included in the FY 1988 Continuing Resolution (Pub. L. 100-202); and (3) certain Amerasians from Vietnam, including U.S. citizens, under title II of the Foreign Operations, Export Financing, and Related Programs Appropriations Acts, 1989 (Pub. L. 100-461), 1990 (Pub. L. 101-167), and 1991 (Pub. L. 101-513). For convenience, the term "refugee" is used in this notice to encompass all such additional persons who are eligible to participate in refugee program services, including the targeted assistance program.

available resources. The final notice reflects adjustments in final allocations to States as a result of additional arrival data.

A notice of proposed allocations of targeted assistance funds was published for public comment in the **Federal Register** on March 10, 1999 (64 FR 11927).

**DATES:** The closing date for submission of applications is September 9, 1999. See Part IV of this announcement for more information on submitting applications.

**FOR FURTHER INFORMATION CONTACT:** Gayle Smith, Acting Director, Division of Refugee Self-Sufficiency, Office of Refugee Resettlement, 370 L'Enfant Promenade, S.W., 6th Floor, Washington, D.C. 20447 Telephone (202) 205-3590, or e-mail: [gsmith@acf.dhhs.gov](mailto:gsmith@acf.dhhs.gov).

*For Further Information on Application Procedures:* States should contact their State Analyst in ORR.

**SUPPLEMENTARY INFORMATION:** This program announcement consists of four parts:

Part I. General Information

Background—program purpose and scope, legislative authority.

Discussion of Comments Received, Funding Availability, Use of Funds, Assurances/Information, Local Program Administration.

Project and Applicant Eligibility—Qualification and Allocation, Funding Priorities, Eligible Applicants, project and budget periods, multiple applications.

Part II: The Project Description

Part III: The Review Process—intergovernmental review, initial ACF screening, evaluation criteria and application review.

Part IV: The Application—application materials, development and submission.

Paperwork Reduction Act of 1995 (Pub. L. 104-13): Public reporting burden for this collection of information is estimated to average four hours per response, including the time for reviewing instructions, gathering and maintaining the data needed, and reviewing the collection of information. The following information collections are included in the program announcement: OMB Approval No. 0970-0139, ACF UNIFORM PROJECT DESCRIPTION (UPD), which expires 10/31/2000, and OMB Approval No. 0970-0036, ORR-6, Quarterly Performance Report (QPR), which expires 7/31/2002. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.