Board of Governors of the Federal Reserve System, September 23, 1997.

Jennifer J. Johnson,

Deputy Secretary of the Board.

[FR Doc. 97–25660 Filed 9–25–97; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request; Proposed Projects

Title: Refugee Resettlement Program Estimates: CMA, ORR–1.

OMB No.: 0970–0030.

Description: ORR reimburses, to the extent of available appropriations, certain non-Federal costs for the provision of cash and medical assistance to refugees, along with allowable expenses in the administration of the Refugee Resettlement Program. ORR needs sound State estimates of likely expenditures for refugee cash, medical, and administrative (CMA) expenditures so that it can anticipate Federal costs in upcoming quarters. If Federal costs are anticipated to exceed budget allocations, ORR must take steps to reduce Federal expenses, such as limiting the number of months of eligibility for Refugee Cash Assistance (RCA) and Refugee Medical Assistance (RMA).

To meet the need for reliable State estimates of anticipated expenses, ORR has developed a single-page form in which States estimate the average number of recipients for each category of assistance, the average unit cost over the next 12 months, and the expense for the overall administration of the program. This form, the ORR–1 (formerly Form FSA–601) must be submitted prior to the beginning of each Federal fiscal year. Without this information, ORR would be out of compliance with the intent of its legislation and otherwise unable to estimate program costs adequately.

In addition, the ORR–1 serves as the State's application for reimbursement of its CMA expenses. Submission of this form is thus required by section 412(a)(4) of the Immigration and Nationality Act which provides that ''no grant or contract may be awarded under this section unless an appropriate proposal and application * * * are submitted to, and approved by, the appropriate administering official.''

Respondents: State, Local or Tribal Govt.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–1	24	1	.5	24

Estimated Total Annual Burden Hours: 24

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Information Service, Division of Information Resource Management Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: September 22, 1997.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 97–25603 Filed 9–25–97; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 96F–0493]

Gerard T. O'Brien; Denial Without Prejudice of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying 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 petitioner did not provide sufficient data and information for the agency to conclude that the proposed use of the food additive is safe, or that it will have its intended technical effect.

DATES: Written objections and request for a hearing by October 27, 1997.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

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** on 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 acting on any food additive petition, FDA must determine whether the proposed use of the additive under the conditions of use to be specified in the regulation is safe (section 409(c)(3)(A) of the Federal Food, Drug,

and Cosmetic Act (the act) (21 U.S.C. 348(c)(3)(A))). The burden is on the petitioner to submit to FDA data and information that are adequate to provide the basis for such a determination. The data and information must include all studies, whether favorable or adverse, relevant to the safety of the food additive and relevant to whether the food additive will achieve its intended physical or technical effect.

FAP 7A4530 was submitted to the agency on September 24, 1987, as FAP 7A4045. The agency found that the petition did not meet the minimum requirements for filing in accordance with § 171.1(c) (21 CFR 171.1(c)). Despite FDA requests to petitioner for data and information to correct the deficiencies (Refs. 1, 2, and 3), the petitioner failed to submit such data and information to demonstrate that the food additive will achieve its intended technical effect, and that it is safe for the intended use. Specifically, the petitioner 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. In addition, the petitioner failed to provide data and information on whether oxidative effects of hydrogen peroxide occur on poultry as a result of the proposed use.

Consequently, FDA requested that the petitioner submit laboratory data to demonstrate that there is reduced bacterial contamination on poultry processed with hydrogen peroxide and sodium bicarbonate, to provide TBA (2-thiobarbituric acid, a representative measure of lipid oxidation) values in skin/fat and meat from processed poultry, and to provide the basis to estimate the amount of hydrogen peroxide that reacts with poultry during the proposed treatment. FDA requested this information to: (1) Determine the bacteriocidal effectiveness of the petitioned use of the additive, (2) assess the degree of oxidation of poultry lipids by hydrogen peroxide, and (3) estimate the human dietary exposure to oxidation products that might be formed in the chicken during processing and might remain until consumption. The petitioner failed to submit this information that the agency had requested in several letters. Without this information the agency is not able to determine the microbiological efficacy and safety of treating fresh poultry with a mixture of hydrogen peroxide and sodium bicarbonate. This information is essential for the agency to determine whether the proposed use of this food additive is safe, and whether it will achieve its intended technical effect.

FDA has several safety concerns regarding the petitioned use of the mixture of hydrogen peroxide and sodium bicarbonate that would be addressed by the data and information that FDA requested from the petitioner. One concern is that this mixture may not kill significant numbers of the pathogenic microbes on the surface of the chicken skin. Thus, human exposure to these pathogens could be higher with the use of the mixture of hydrogen peroxide and sodium bicarbonate than human exposure to these pathogens from currently used methods for killing bacteria on the surface of chicken skin, for example processing poultry in chlorinated water. In addition, it is possible that the mixture of hydrogen peroxide and sodium bicarbonate will kill off nonpathogenic microbes, giving a competitive advantage to the pathogens, so that they may reproduce to higher numbers. Another safety concern is that hydrogen peroxide is a strong oxidant that could interact with lipids and other biological constituents in the skin of chicken to form oxidation products. These oxidation products could potentially be mutagenic and represent a hazard to consumers.

Thus, on March 9, 1992, because the petitioner failed to correct the deficiencies in the petition as previously described, FDA notified the petitioner that it would not continue to evaluate this submitted petition (Ref. 4).

Although the petitioner continued to correspond with the agency, at no time did he submit the requested information. In a September 18, 1995, letter to FDA the petitioner asked whether he had exhausted his administrative remedies. Before receiving a response from FDA, on December 6, 1995, the petitioner filed, in the U.S. District Court for the Northern District of Georgia, Gainesville Division, a pro se complaint against FDA and others alleging patent and copyright infringement, antitrust violations, Racketeer Influenced and Corrupt Organizations Act violations, fraud, and various torts. The Court dismissed the complaints without prejudice on March 20, 1996.

In a letter dated October 16, 1996, the agency responded to the petitioner's earlier question on whether the petitioner had exhausted his administrative remedies. In that letter, the agency stated that the petitioner had not exhausted his administrative remedies, and that he could either file a new petition that would include the supplemental information requested by the agency or send a written request to FDA asking the agency to file the petition as submitted in accordance with § 171.1(i)(1). The petitioner responded in a November 4, 1996, letter indicating that he wanted FDA to approve the proposed use of the additive and did not intend to supplement the petition. Therefore, on December 10, 1996, FDA filed the petition as submitted in accordance with § 171.1(i)(1) (62 FR 101, January 2, 1997).

The filed petition (FAP 7A4530) proposed 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. After reviewing the petition, which the petitioner did not supplement in order to correct previously identified deficiencies, the agency concluded that the petition does not contain data and information that would allow the agency to conclude that the food additive is safe and that it will achieve its intended technical effect. Therefore, FDA is denying FAP 7A4530 in accordance with 21 CFR 171.100(a).

References

The following information has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Letter dated January 6, 1988, from FDA to the petitioner.

2. Letter dated April 14, 1988, from FDA to the petitioner.

3. Letter dated June 15, 1989, from FDA to the petitioner.

4. Letter dated March 9, 1992, from FDA to the petitioner.

Any person who will be adversely affected by the foregoing order may at any time on or before October 27, 1997, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered. Each numbered objection shall show wherein the person filing will be adversely affected by the order, specify with particularity the provisions of the order to which objection is made, and state the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include

such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the order may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 17, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–25588 Filed 9–25–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0398]

Guidance for Industry on Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry entitled ''Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations.'' This guidance document is intended to provide recommendations to pharmaceutical sponsors who intend to develop documentation in support of an in vitro/in vivo correlation (IVIVC) for an oral extended release (ER) drug product for submission in a new drug application (NDA), abbreviated new drug application (ANDA), or antibiotic drug application (ANDA/AADA).

DATES: Written comments may be submitted at any time.

ADDRESSES: Submit written requests for single copies of ''Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations'' 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 that office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Ramana Uppoor, Center for Drug Evaluation and Research, HFD–860, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5305.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance document for industry entitled ''Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations.'' This guidance document provides recommendations to pharmaceutical sponsors who intend to develop documentation in support of an IVIVC for an oral ER drug product for submission in an NDA, ANDA, or AADA. The guidance presents a comprehensive perspective on: (1) Methods of developing an IVIVC and evaluating its predictability; (2) using an IVIVC to set dissolution specifications; and (3) applying an IVIVC as a surrogate for in vivo bioequivalence when it is necessary to document bioequivalence during the initial approval process or because of certain preapproval or postapproval changes, e.g., formulation, equipment, process, and manufacturing site changes.

This guidance document represents the agency's current thinking on the development, evaluation, and application of in vitro/in vivo correlations for an oral ER drug product for submission in an NDA, ANDA, or AADA. 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.

Interested persons may, at any time, submit written comments on the guidance to the Dockets Management Branch (address above). 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.

An electronic version of this guidance is also available on the Internet at http://www.fda.gov/cder/guidance/index.htm.

Dated: September 18, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–25514 Filed 9–25–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4235–N–22]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

EFFECTIVE DATE: September 26, 1997.

FOR FURTHER INFORMATION CONTACT: Mark Johnston, Department of Housing and Urban Development, Room 7256, 451 Seventh Street SW, Washington, DC 20410; telephone (202) 708–1226; TDD number for the hearing- and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1988 court order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: September 18, 1997.

Fred Karnas, Jr.,

Deputy Assistant Secretary for Economic Development.

[FR Doc. 97–25183 Filed 9–25–97; 8:45 am]

BILLING CODE 4210–29–M