burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.


Section 412(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 350a(e)) provides that if the manufacturer of an infant formula has knowledge that reasonably supports the conclusion that an infant formula processed by that manufacturer has left its control and may not provide the nutrients required in section 412(i) of the act or is otherwise adulterated or misbranded, the manufacturer must promptly notify the Secretary of Health and Human Services (the Secretary). If the Secretary determines that the infant formula presents a risk to human health, the manufacturer must immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary. Section 412(f)(2) of the act states that the Secretary shall by regulation prescribe the scope and extent of recalls of infant formula necessary and appropriate for the degree of risk to human health presented by the formula subject to recall. FDA’s infant formula recall regulations (part 107, subpart E (21 CFR part 107, subpart E)) implement these statutory provisions.

Section 107.230 requires each recalling firm to: (1) Evaluate the hazard to human health, (2) devise a written recall strategy, (3) promptly notify each affected direct account (customer) about the recall, and (4) furnish the appropriate FDA district office with copies of these documents. If the recalled formula presents a risk to human health, the recalling firm must also request that each establishment that sells the recalled formula post (at point of purchase) a notice of the recall and provide FDA with a copy of the notice. Section 107.240 requires the recalling firm to: (1) Notify the appropriate FDA district office of the recall by telephone within 24 hours, (2) submit a written report to that office within 14 days, and (3) submit a written status report at least every 14 days until the recall is terminated. Before terminating a recall, the recalling firm is required to submit a recommendation for termination of the recall to the appropriate FDA district office and wait for written FDA concurrence (§107.250). Where the recall strategy or implementation is determined to be deficient, FDA may require the firm to change the extent of the recall, carry out additional effectiveness checks, and issue additional notifications (§107.260). In addition, to facilitate location of the product being recalled, the recalling firm is required to maintain distribution records for at least 1 year after the expiration of the shelf life of the infant formula (§107.280).

The reporting and recordkeeping requirements described previously are designed to enable FDA to monitor the effectiveness of infant formula recalls in order to protect babies from infant formula that may be unsafe because of contamination or nutritional inadequacy or otherwise adulterated or misbranded. FDA uses the information collected under these regulations to help ensure that such products are quickly and efficiently removed from the market. If manufacturers were not required to provide this information to FDA, FDA’s ability to ensure that recalls are conducted properly would be greatly impaired.

FDA estimates the burden of this collection of information as follows:

<table>
<thead>
<tr>
<th>21 CFR Section</th>
<th>No. of Respondents</th>
<th>Annual Frequency per Response</th>
<th>Total Annual Responses</th>
<th>Hours per Response</th>
<th>Total Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>107.230</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>4,500</td>
<td>4,500</td>
</tr>
<tr>
<td>107.240</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1,482</td>
<td>1,482</td>
</tr>
<tr>
<td>107.250</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>120</td>
<td>120</td>
</tr>
<tr>
<td>107.260</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>650</td>
<td>650</td>
</tr>
<tr>
<td>Total</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>6,752</td>
<td></td>
</tr>
</tbody>
</table>

† There are no capital costs or operating and maintenance costs associated with this collection of information.

Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. No burden has been estimated for the recordkeeping requirement in §107.280 because these records are maintained as a usual and customary part of normal business activities. Manufacturers keep infant formula distribution records for the prescribed period as a matter of routine business practice.

The reporting burden estimate is based on agency records, which show that there are five manufacturers of infant formula and that there have been three recalls in the last 3 years, or one recall annually.

Dated: February 8, 1999.

William K. Hubbard, Associate Commissioner for Policy Coordination.

[FR Doc. 99-4338 Filed 2-22-99; 8:45 am]
BILLING CODE 4160-01-F

DEPARTMENT OF THE INTERIOR
Fish and Wildlife Service

AGENCY: Fish and Wildlife Service, Department of the Interior.


SUMMARY: The Fish and Wildlife Service (Service) is preparing a Comprehensive Conservation Plan (CCP) and National Environmental Policy Act (NEPA) document for the San Joaquin River National Wildlife Refuge. This notice advises the public that the Service intends to gather information necessary to prepare a CCP and environmental documents pursuant to the National Wildlife Refuge System Administration Act of 1966, as amended, and NEPA. The public is invited to participate in the planning process. The Service is furnishing this notice in compliance with the Service CCP policy:

(1) To advise other agencies and the public of our intentions,
DEPARTMENT OF THE INTERIOR
Fish and Wildlife Service
Receipt of Application for Endangered Species Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of application for endangered species permit.

SUMMARY: The following applicants have applied for permits to conduct certain activities with endangered species. This notice is provided pursuant to section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 et seq.).

DATES: Written data or comments on these applications must be received, at the address given below, by March 25, 1999.

ADDRESSES: Documents and other information submitted with these applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, 1875 Century Boulevard, Suite 200, Atlanta, Georgia 30345 (Attn: David Dell, Permit Biologist). Telephone: 404/679–7313; Facsimile: 404/679–7081.


SUPPLEMENTARY INFORMATION:
Applicant: Regional Administrator, National Marine Fisheries Service, Southeast Region, St. Petersburg, Florida, TE676379–2

The applicant requests renewal of existing authorization to take (harass, capture, temporarily retain, tag, and similar activities) the endangered Atlantic ridley, Lepidochelys kempii, hawksbill, Eretmochelys imbricata, leatherback, Dermochelys coriacea, and green (in Florida), Chelonia mydas, sea turtles; and the threatened green (in remainder of range), loggerhead, Caretta caretta, and olive ridley, Lepidochelys olivacea, sea turtles. Take of these species will occur throughout their respective ranges in North Carolina, South Carolina, Georgia, Florida, Alabama, Mississippi, Louisiana, Texas, Puerto Rico, the U.S. Virgin Islands, the Gulf of Mexico, and the northwestern Atlantic Ocean, and will serve the purpose of enhancement of survival of these species.

Applicant: Steven M. Lohr, Clemson University, Clemson, South Carolina, TE007655–0.