

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

Infant Formula Recall Regulations—21 CFR 107.230, 107.240, 107.250, 107.260, 107.280 (OMB Control Number 0910-0188—Reinstatement)

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 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
107.230	1	1	1	4,500	4,500
107.240	1	1	1	1,482	1,482
107.250	1	1	1	120	120
107.260	1	1	1	650	650
Total					6,752

¹ 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.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

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

ACTION: Notice of Intent to Prepare a Comprehensive Conservation Plan and Associated National Environmental Policy Act Document for the San Joaquin River National Wildlife Refuge,

Stanislaus and San Joaquin Counties, California.

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,

(2) To obtain suggestions and information on the scope of issues to include in the environmental documents, and

(3) To announce a public open house to occur in March, 1999. Information about the time and location of the open house will be published in local media, will be provided to individuals on our mailing list, and will be available by contacting the refuge or planning team leader.

DATES: To ensure that the Service has adequate time to evaluate and incorporate suggestions and other input into the planning process, comments should be received on or before April 9, 1999.

ADDRESSES: Send written comments or requests to be added to the mailing list to the following address: Planning Team Leader—San Joaquin River NWR, California/Nevada Refuge Planning Office, US Fish and Wildlife Service, 2233 Watt Avenue, Suite 230, Sacramento, California, 95825.

FOR FURTHER INFORMATION CONTACT: Leslie Lew, Planning Team Leader, (916) 979-2085, or Scott Frazer, Refuge Operations Specialist, (209) 826-3508.

SUPPLEMENTARY INFORMATION: The National Wildlife Refuge System Administration Act of 1966, as amended, mandates that all lands within the National Wildlife Refuge System are to be managed in accordance with an approved CCP. The CCP will guide management decisions and identify refuge goals, long-range objectives and management strategies for achieving refuge purposes. The planning process will consider many elements, including habitat and wildlife management, habitat protection, cultural resources, and environmental effects. Public input into this planning process is very important. The CCP will provide other agencies and the public with a clear understanding of the desired conditions for the refuges and how the Service will implement management strategies.

The Service is soliciting information from the public via written comments. Interested parties are urged to be added to the Service's mailing list. The Service will send out special mailings, newspaper articles, and announcements to people who are interested in the refuge. These mailings will provide information on how to participate in public involvement for the CCP. Comments received will be used to develop goals, key issues, and habitat management strategies. Additional opportunities for public participation will occur throughout the process, which is expected to be completed in

late 1999. Data collection has been initiated to create computerized mapping, including vegetation, topography, habitat types and existing land uses.

The San Joaquin River National Wildlife Refuge is located west of Modesto, California, within the historic floodplain of the confluences of the San Joaquin, Stanislaus, and Tuolumne Rivers. The Refuge was established in 1987 because of the importance of the area as habitat for the endangered Aleutian Canada goose. This area is the traditional wintering area for virtually the entire population of the Aleutian Canada goose. Refuge lands consist of riparian forest, grasslands, pastures, agricultural fields, and wetlands.

The Refuge also protects other federally listed species, such as the threatened chinook salmon, improves and manages habitat for migratory birds, and conserves native fauna and flora. Currently the Refuge consists of 5,588 acres controlled by the Service within an approved Refuge boundary of 12,877 acres.

The Central Valley of California, which comprises the Sacramento and San Joaquin Valleys, provides winter habitat for about 60 percent of the Pacific flyway waterfowl population. Before the arrival of European settlers, about 4 million acres of wetlands existed in the Central Valley. Today, only about 300,000 acres of wetlands remain in the same area. Preservation, restoration, and management of wetlands, grasslands, and riparian habitat such as that found on the San Joaquin River National Wildlife Refuge, are needed to ensure that adequate wildlife habitat will be available to sustain the population levels of a variety of wildlife species.

The Refuge purpose is to conserve fish, wildlife, and plants which are Federally listed as endangered or threatened species. (16 U.S.C. 1534—Endangered Species Act of 1973).

The outcome of this planning process will be a CCP to guide refuge management for the next 15 years and accompanying NEPA document.

It is estimated that a draft CCP and NEPA document will be made available for public review in fall 2000.

Dated: February 12, 1999.

Michael J. Spear,

Manager, California Nevada Operations, U.S. Fish and Wildlife Service, Sacramento, California.

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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.

FOR FURTHER INFORMATION CONTACT: David Dell, 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 the species.

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