

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N-0136]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Interstate Shellfish Dealers Certificate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 13, 2006

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Interstate Shellfish Dealers Certificate—(OMB Control Number 0910-0021)—Extension

Under 42 U.S.C. 243, FDA is required to cooperate with and aid State and local authorities in the enforcement of their health regulations and is authorized to assist States in the prevention and suppression of communicable diseases. Under this authority, FDA participates with State regulatory agencies, some foreign nations, and the molluscan shellfish industry in the National Shellfish Sanitation Program (NSSP).

NSSP is a voluntary, cooperative program to promote the safety of molluscan shellfish by providing for the classification and patrol of shellfish growing waters and for the inspection and certification of shellfish processors.

Each participating State and foreign nation monitors its molluscan shellfish processors and issues certificates for those that meet the State or foreign shellfish control authority's criteria. Each participating State and nation provides a certificate of its certified shellfish processors to FDA on Form FDA 3038, "Interstate Shellfish Dealer's Certificate." FDA uses this information to publish the "Interstate Certified Shellfish Shippers List," a monthly comprehensive listing of all molluscan shellfish processors certified under the cooperative program. If FDA did not collect the information necessary to compile this list, participating States would not be able to identify and keep out shellfish processed by uncertified processors in other States and foreign nations. Consequently, NSSP would not be able to control the distribution of uncertified and possibly unsafe shellfish in interstate commerce, and its effectiveness would be nullified.

In the **Federal Register** of April 11, 2006 (71 FR 18339), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
3038	39	62	2,418	.10	242

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

This estimate is based on FDA's experience and the number of certificates received in the past 3 years.

Dated: October 5, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Funding Opportunity Number: HHS-2007-IHS-TSGP-0002

Tribal Self-Governance Program; Negotiation Cooperative Agreement; New Funding Cycle for Fiscal Year 2007

CFDA Number: 93.210.

Key Dates: Applications Due—November 16, 2006.

Objective Review Committee to Evaluate Applications—December 7-8, 2006.

Anticipation Project Start Date—January 15, 2007.

I. Funding Opportunity Description

The purpose of the program is to award cooperative agreements that provide negotiation resources to Tribes interested in participating in the Tribal Self-Governance Program (TSGP) as authorized by Title V, Tribal Self-Governance Amendments of 2000 of the Indian Self-Determination and Education Assistance Act of Public Law (Pub. L.) 93-638, as amended. There is limited competition under this announcement because the authorizing legislation, Pub. L. 106-260, Title V, restricts eligibility to Tribes that meet specific criteria. (Refer to Section III. (1.) (A.), Eligible Applicants in this announcement.) The TSGP is designed to promote self-determination by allowing Tribes to assume more control

of Indian Health Service (IHS) programs and services through compacts negotiated with the IHS. The Negotiation Cooperative Agreement provides Tribes with funds to help cover the expenses involved in preparing for and negotiating with the IHS and assists eligible Indian Tribes to prepare for Compacts and Funding Agreements (FAs) with an effective date of January 15, 2007.

The Negotiation Cooperative Agreement provides resources to assist Indian Tribes to conduct negotiation activities that include but are not limited to:

1. Determine what programs, services, functions, and activities (PSFA's) will be negotiated.
 2. Identification of Tribal shares that will be included in the FA.
 3. Development of the terms and conditions that will be set forth in a Compact and Funding (FA).
- The award of a Negotiation Cooperative Agreement is not required