

Dated: July 9, 1998.

**Michael A. Friedman,**

*Deputy Commissioner for Operations.*

[FR Doc. 98-19030 Filed 7-16-98; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 98D-0393]

#### National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guide entitled "National Shellfish Sanitation Program (NSSP) Guide for the Control of Molluscan Shellfish." The guide was developed cooperatively by FDA and the Interstate Shellfish Sanitation Conference (ISSC) with the intent of replacing the existing NSSP Manuals of Operation, Parts I and

II. The guide contains a Model Ordinance for ensuring that only safe and sanitary shellfish are offered for sale in interstate commerce. Language contained in the Model Ordinance has been codified for easy adoption into law or regulation by State regulatory agencies. The guide also includes documentation supportive of the codified language of the Model Ordinance, including: The NSSP's history, public health reasons and explanations specific to the guidelines contained in the Model Ordinance, NSSP guidance documents, suggested NSSP forms, shellfish policy setting documents, pertinent Federal regulations, and references to the public health reasons and explanations. These supportive materials aid in ensuring consistent and uniform implementation of a national shellfish safety program.

**DATES:** Comments on the guide may be submitted at any time.

**ADDRESSES:** Submit written comments on the guide to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for single copies of the

guide entitled "National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish" to the contact person in the nearest regional office listed in the **SUPPLEMENTARY INFORMATION** section of this document. Send two self-addressed adhesive labels to assist in processing your requests. An electronic version of the guide is available on the World Wide Web at (<http://www.issc.org>).

**FOR FURTHER INFORMATION CONTACT:** Paul W. DiStefano, Office of Seafood, Center for Food Safety and Applied Nutrition (HFS-417), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3150, FAX: 202-418-3198, e-mail: "pdistefa@bangate.fda.gov", or the contact person in the nearest regional office as listed in the **SUPPLEMENTARY INFORMATION** section of this document.

**SUPPLEMENTARY INFORMATION:** Copies of the guide entitled "National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish" can be obtained from the nearest regional office as follows:

FDA Addresses	Contact Person
Stoneham District Office, State Programs Branch, One Montvale Ave., Stoneham, MA 02180	David G. Field
New York Regional Office, 850 Third Ave., Brooklyn, NY 11232-1593	Jerry H. Mulnick
Baltimore District Office, Investigations Branch, 900 Madison Ave., Baltimore, MD 21201	Al A. Ondis
Atlanta Regional Office, State Cooperative Programs, 60 Eighth St. NE., Atlanta, GA 30309	James A. Casey
Charleston Resident Post, 334 Meeting St., rm. 505, P.O. Box 21077, Charleston, SC 29413	Donald Hesselman
Tallahassee Resident Post, Hobbs Federal Bldg., 227 North Bronough St., suite 4150, Tallahassee, FL 32301	Marc B. Glatzer
Baton Rouge Resident Post, 5353 Essen Lane, suite 220, Baton Rouge, LA 70809	John E. Veazey
Detroit District Resident Post, 1560 East Jefferson Ave., Detroit, MI 48207	Nicholas L. Majerus
Dallas Regional Office, 7920 Elmbrook Dr., suite 102, Dallas, TX 75247	David A. Blevins
Seattle District Office, 100 Second Ave., suite 2400, Seattle, WA 98104	Tim E. Sample
Shellfish Safety Team (HFS-628), 200 C St. SW., Washington, DC 20204	Stanley D. Ratcliffe

FDA is the Federal agency responsible for administration of the NSSP. The NSSP is a voluntary program in which State shellfish control agencies, the shellfish industry, FDA, and other Federal agencies participate. The NSSP, which has been in existence since 1925, addresses the sanitary control of fresh and frozen molluscan shellfish (oysters, clams, mussels, and scallops) offered for sale in interstate commerce. To promote uniform administrative and technical controls, the NSSP has developed and maintained recommended shellfish

control practices for adoption by member States. These control practices, which were initially published as the NSSP Manuals of Operation, Parts I and II, are contained in the guide "NSSP Guide for the Control of Molluscan Shellfish."

In 1982, interested State officials and members of the shellfish industry formed the ISSC to provide a structure wherein State regulatory authorities could meet on a regular basis to discuss ways to improve shellfish sanitation and safety. FDA and the ISSC entered into

a memorandum of understanding (MOU) that was published in the **Federal Register** of March 30, 1984 (49 FR 12751), agreeing, among other things, that FDA would provide technical assistance to the ISSC. The ISSC in turn would help FDA develop or revise program criteria and guidelines in the NSSP Manuals of Operation. Based on the MOU, and in cooperation with the ISSC, FDA periodically publishes revisions of the NSSP

Manuals of Operation based on resolutions adopted by voting delegates of the ISSC and with which FDA concurs.

The success of the NSSP is largely dependent on the States adopting and implementing the recommended shellfish control practices for the operation of effective programs. These recommended practices, which traditionally have been incorporated into the NSSP Manuals of Operation have been reconstituted in the form of a "NSSP Guide for the Control of Molluscan Shellfish." The purpose of the "NSSP Guide for the Control of Molluscan Shellfish" handbook is twofold. First, it serves to redraft existing guidelines contained in the NSSP Manuals of Operation into a NSSP Model Ordinance, which contains language that can be readily codified into law or regulation by a State. Second, it sets forth supportive documentation pertinent to the codified language of the Model Ordinance, including: The NSSP's history, public health reasons and explanations specific to the guidelines contained in the Model Ordinance, NSSP guidance documents, suggested NSSP forms, shellfish policy-setting documents, pertinent Federal regulations, and references to the public health reasons and explanations.

Redrafting of the NSSP Manuals of Operation was accomplished through the efforts of the ISSC working in cooperation with FDA. This effort began in 1989 and continued through December 1997. Wherever possible, the concepts and language contained in the NSSP Manuals of Operation were used in the NSSP Model Ordinance. Where language did not exist to explain a requirement (e.g., flow charts), an explanation was developed. In cases where the intent of the NSSP Manuals of Operation was not clear, new definitions were developed. Apparently conflicting requirements in the Manuals of Operation were resolved by selecting the requirement that most clearly reflected the intent of the NSSP or by selecting the more restrictive requirement.

In 1997, FDA was asked by the ISSC to adopt the Model Ordinance. FDA recognized that if it were to do so, the NSSP Model Ordinance would be a FDA guideline, and as such, it would be subject to the policy of FDA relating to the development, issuance, and use of guidance documents, as expressed in the **Federal Register** of February 27, 1997 (62 FR 8961 at 8969 through 8971). This policy states that the public will be afforded an opportunity to comment on guidance documents in accordance with Level 1 Good Guidance Practices

documents as set out in the **Federal Register** of February 27, 1997 (62 FR 8961).

The annual meeting of the ISSC, in the past and again at the July 1997 meeting, provided an essential forum for the development of revisions to the NSSP. The participatory process that occurs at this meeting serves the purposes and principles set forth in the agency's guidance documents policy. Therefore, in a notice published in the **Federal Register** of June 26, 1997 (62 FR 34480), FDA announced that the Model Ordinance was to be discussed at the July 1997 ISSC meeting, and that this meeting would act as the forum for public comment on the Model Ordinance as an FDA guidance document. FDA requested comment on the procedure, but received none.

With concurrence from FDA, the NSSP Model Ordinance was adopted by the ISSC at its July 1997 meeting in Sturbridge, MA. With this notice, FDA is announcing the availability of the Model Ordinance as contained within the guide "NSSP Guide for the Control of Molluscan Shellfish." At the Federal level, the Model Ordinance has the status of guidance and, as such, does not create or confer any rights for or on any person and does not operate to bind FDA or the public. However, through their participation in the NSSP and the ISSC, participating States have voluntarily agreed to follow the Model Ordinance as the requirements which are minimally necessary for membership.

The public may comment on this document at anytime. The public may comment in one of two ways: (1) By attending the ISSC conference held annually for the purpose of, among other things, considering changes to the Model Ordinance; or (2) by commenting to FDA. Those comments that the agency finds meritorious will be offered by FDA for consideration and vote at a subsequent ISSC.

The NSSP Model Ordinance will facilitate uniform adoption of the recommended shellfish control practices by States for regulation of their shellfish industry. Adoption of the NSSP Model Ordinance by each State will strengthen the credibility of the National Shellfish Sanitation Program and the "Interstate Certified Shellfish Shippers List" (ICSSL), which identifies shellfish dealers certified by their State of residence as being in compliance with NSSP guidelines. Assurance that all shellfish dealers are meeting the minimum criteria will foster confidence in product safety.

Interested persons may, at any time, submit to the Dockets Management

Branch (address above) written comments on the guide. Two copies of any comments should 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. At the discretion of FDA, received comments will be used to develop issues for submission to the ISSC for consideration at its July 1999, annual meeting.

Dated: July 8, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute of Dental Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Commission:* National Institute of Dental Research Special Emphasis Panel, Emphasis Panel 44 & 45.

*Date:* July 26-28, 1998.

*Time:* 8:00 am to 5:00 pm.

*Agenda:* To review and evaluate grant applications.

*Place:* Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

*Contact Person:* Yong A. Shin, PhD, Scientific Review Administrator, 4500 Center Drive, Natcher Building, Rm. 4AN44F, National Institutes of Health, Bethesda, MD 20892, (301) 594-2372.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalog of Federal Domestic Assistance Program Nos. 93.121, Oral Diseases and