

information that are a usual and customary part of businesses' normal activities. For example, the tagging and labeling of molluscan shellfish (21 CFR 1240.60) is a customary and usual practice among seafood processors.

Consequently, the estimates in table 1 account only for information collection and recording requirements attributable to part 123.

Description of Respondents:
Respondents to this collection of

information include processors and importers of seafood.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN ¹

| 21 CFR Section ² | Number of recordkeepers | Number of records per recordkeeper ³ | Total annual records | Average burden per recordkeeping ⁴ | Total hours |
|---|-------------------------|---|----------------------|---|------------------|
| 123.6(a), (b), and (c); Prepare hazard analysis and HACCP plan. | 50 | 1 | 50 | 16 | 800 |
| 123.6(c)(5); Undertake and prepare records of corrective actions. | 15,000 | 4 | 60,000 | 0.30 (18 minutes) | 18,000 |
| 123.8(a)(1) and (c); Reassess hazard analysis and HACCP plan. | 15,000 | 1 | 15,000 | 4 | 60,000 |
| 123.12(a)(2)(ii); Verify compliance of imports and prepare records of verification activities. | 4,100 | 80 | 328,000 | 0.20 (12 minutes) | 65,600 |
| 123.6(c)(7); Document monitoring of critical control points. | 15,000 | 280 | 4,200,000 | 0.30 (18 minutes) | 1,260,000 |
| 123.7(d); Undertake and prepare records of corrective actions due to a deviation from a critical limit. | 6,000 | 4 | 24,000 | 0.10 (6 minutes) | 2,400 |
| 123.8(d); Maintain records of the calibration of process-monitoring instruments and the performing of any periodic end-product and in-process testing. | 15,000 | 47 | 705,000 | 0.10 (6 minutes) | 70,500 |
| 123.11(c); Maintain sanitation control records. | 15,000 | 280 | 4,200,000 | 0.10 (6 minutes) | 420,000 |
| 123.12(c); Maintain records that verify that the fish and fishery products they offer for import into the United States were processed in accordance with the HACCP and sanitation provisions set forth in part 123. | 4,100 | 80 | 328,000 | 0.10 (6 minutes) | 32,800 |
| 123.12(a)(2); Prepare new written verification procedures to verify compliance of imports. | 41 | 1 | 41 | 4 | 164 |
| Total | | | | | 1,930,264 |

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

² These estimates include the information collection requirements in the following sections: § 123.16—Smoked Fish—process controls (see § 123.6(b)); § 123.28(a)—Source Controls—molluscan shellfish (see § 123.6(b)); § 123.28(c) and (d)—Records—molluscan shellfish (see § 123.6(c)(7)).

³ Based on an estimated 280 working days per year.

⁴ Estimated average time per 8-hour work day unless one-time response.

Based on a review of the information collection since our last OMB approval, we have made no adjustments to our burden estimate. We base this hour burden estimate on our experience with the application of HACCP principles in food processing. Further, the burdens have been estimated using typical small seafood processing firms as a model because these firms represent a significant proportion of the industry. The hour burden of HACCP recordkeeping activities will vary considerably among processors and importers of fish and fishery products, depending on the size of the facility and complexity of the HACCP control scheme (i.e., the number of products and the number of hazards controlled); the daily frequency that control points

are monitored and values recorded; and also on the extent that data recording time and cost are minimized by the use of automated data logging technology. The burden estimate does not include burden hours for activities that are a usual and customary part of businesses' normal activities. For example, the tagging and labeling of molluscan shellfish (§ 1240.60) is a customary and usual practice among seafood processors.

Dated: August 26, 2019.
Lowell J. Schiller,
Principal Associate Commissioner for Policy.
[FR Doc. 2019-18987 Filed 9-3-19; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-3793]

General Hospital and Personal Use Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice, establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee

meeting of the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on November 6 and 7, 2019, from 8 a.m. to 6 p.m.

ADDRESSES: DoubleTree by Hilton, Washington DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel's telephone number is 301-977-8900. <https://doubletree3.hilton.com/en/hotels/maryland/doubletree-by-hilton-washington-dc-north-gaithersburg-GAIGWDT/index.html>. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/advisory-committees/about-advisory-committees/common-questions-and-answers-about-fda-advisory-committee-meetings>. You may submit comments as follows:

FDA is establishing a docket for public comments on this meeting. The docket number is FDA-2019-N-3793. The docket will close on December 6, 2019. Submit either electronic or written comments on this public meeting to the docket by December 6, 2019. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 6, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 6, 2019. Comments received by mail/hand delivery/courier (for written/paper submission) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before October 21, 2019, will be provided to the Committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submission" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-N-3793 for "The General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments." Received comments those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states

"THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Patricio Garcia, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66 Rm. G610, Silver Spring, MD 20993-0002, patricio.garcia@fda.hhs.gov, (301) 796-6875, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's website at <https://www.fda.gov/advisory-committees> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: On November 6 and 7, 2019, the committee will discuss the topic of industrial ethylene oxide (EtO) sterilization of medical devices and its role in maintaining public health as

well as the risks of infection with reprocessed duodenoscopes. Subject matter of the panel meeting will include potential methods and expert assessment of how to reduce EtO emissions to the environment from medical device sterilization processes without compromising assurance of sterility or effective processing of medical devices. The panel will also discuss recommendations to reduce the risk of infection from reprocessed duodenoscopes.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be publicly available at the location of the advisory committee meeting and the background material will be posted on FDA's website after the meeting. Background material will be available at <https://www.fda.gov/advisory-committees/advisory-committee-calendar>. Scroll down to the appropriate advisory committee meeting link.

FDA plans to provide a live webcast of the November 6 and 7, 2019, meeting of the General Hospital and Personal Use Devices Panel of the Medical Devices Advisory Committee. While CDRH is working to make webcasts available to the public for all advisory committee meetings, there are instances where the webcast transmission is not successful; staff will work to re-establish the transmission as soon as possible. The link for the webcast is available at: <https://collaboration.fda.gov>. Webcast information, including the website address for the webcast, are the following, for their respective days:

November 6, 2019: <http://>

fda.yorkcast.com/webcast/Play/eed34f9b1f448f9a1f6ad05a4b98d7d1d

November 7, 2019: <http://>

fda.yorkcast.com/webcast/Play/49c5a76d5d1c422d8da028441ab557de1d

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the Committee. Written submissions may be made to the contact person on or before October 22, 2019. Oral presentations from the public will be scheduled on November 6, 2019, between approximately 1:30 p.m. and 2 p.m. and from 3:50 p.m. to 4:20 p.m. and on November 7, 2019, between approximately 1:20 p.m. and 1:50 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief

statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 16, 2019. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 17, 2019.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Artair Mallett, at Artair.Mallett@fda.hhs.gov or 301-796-9638 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings>.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.
[FR Doc. 2019-19079 Filed 9-3-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Meeting of the Advisory Committee on Training in Primary Care and Dentistry

AGENCY: Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Training in Primary Care

and Dentistry (ACTPCMD) has scheduled a public meeting. Information about ACTPCMD and the agenda for this meeting can be found on the ACTPCMD website at: <https://www.hrsa.gov/advisory-committees/primarycare-dentist/index.html>.

DATES: October 31, 2019, 10:00 a.m.–5:00 p.m. Eastern Time.

ADDRESSES: This meeting will be held by webinar.

- **Webinar link:** <https://hrsa.connectsolutions.com/ACTPCMD>.
- **Conference Call in number:** (888) 455-0640; Passcode: HRSA COUNCIL (voice response).

FOR FURTHER INFORMATION CONTACT:

Kennita Carter, MD, Senior Advisor and Designated Federal Official, Division of Medicine and Dentistry, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; phone (301) 945-3505; or email BHWACTPCMD@hrsa.gov.

SUPPLEMENTARY INFORMATION:

ACTPCMD provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under section 747 of Title VII of the Public Health Service (PHS) Act, as it existed upon the enactment of Section 749 of the PHS Act in 1998.

At this meeting, ACTPCMD will discuss matters concerning innovations in training in primary care medicine and dentistry as well as ACTPCMD's upcoming report and recommendations. Agenda items are subject to change as priorities dictate. Refer to the ACTPCMD website for any updated information concerning the meeting. An agenda will be posted on the website at least 14 calendar days before the meeting. Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to ACTPCMD should be sent to Kennita Carter using the contact information above at least three business days prior to the meeting.

Individuals who plan to attend and need special assistance or another reasonable accommodation should notify Kennita Carter at the address and phone number listed above at least 10 business days before the meeting.

Maria G. Button,

Director, Division of the Executive Secretariat.
[FR Doc. 2019-19035 Filed 9-3-19; 8:45 am]

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