Dated: April 24, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08609 Filed 4–26–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–4465]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Administrative Detention and Banned Medical Devices

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 May 29, 2019.

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: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0114. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

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.

Administrative Detention and Banned Medical Devices—21 CFR 800.55(g)(1), (g)(2), and (k), 895.21(d), and 895.229(a)

OMB Control Number 0910–0114—Extension

FDA has the statutory authority under section 304(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 334(g)) to detain during established inspections devices that are believed to be adulterated or misbranded. Section 800.55 (21 CFR 800.55), on administrative detention, includes among other things certain reporting requirements (§ 800.55(g)(1) and (2)) and recordkeeping requirements (§ 800.55(k)). Under § 800.55(g), an appellant of a detention order must show documentation of ownership if devices are detained at a place other than that of the appellant. Under § 800.55(k), the owner or other responsible person must supply records about how the devices may have become adulterated or misbranded, in addition to records of distribution of the detained devices. These recordkeeping requirements for administrative detentions permit FDA to trace devices for which the detention period expired before a seizure is accomplished or injunctive relief is obtained.

FDA also has the statutory authority under section 516 of the FD&C Act (21 U.S.C. 360f) to ban devices that present substantial deception or an unreasonable and substantial risk of illness or injury. Section 895.21 (21 CFR 895.21), on banned devices, contains certain reporting requirements. Section 895.21(d) describes the procedures for banning a device when the Commissioner of Food and Drugs (the Commissioner) decides to initiate such a proceeding. Under 21 CFR 895.22, a manufacturer, distributor, or importer of a device may be required to submit to FDA all relevant and available data and information to enable the Commissioner to determine whether the device presents substantial deception, unreasonable and substantial risk of illness or injury, or unreasonable, direct, and substantial danger to the health of individuals.

During the past several years, there has been an average of less than one new administrative detention action per year. Each administrative detention will have varying amounts of data and information that must be maintained.

In the **Federal Register** of December 21, 2018 (83 FR 65683), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Documentation of ownership—800.55(g)	1	1	1	25	25
Banned devices reporting requirements—895.21(d)(8) and 895.22(a)	26	1	26	16	416
Total					441

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records regarding device adulteration or misbranding and records of distribution of detained devices—800.55(k)	1	1	1	20	20

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: April 24, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–08558 Filed 4–26–19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Workshop

Notice is hereby given of a workshop convened by the Interagency Autism Coordinating Committee (IACC).

The purpose of the 2019 IACC Workshop, Addressing the Health Outcome Needs of People with Autism Spectrum Disorder (ASD), is to convene a working group of the IACC that will focus on the health outcome needs of individuals with ASD. The working group will use this workshop to discuss health epidemiology, patient-provider interactions, and co-occurring health conditions that affect individuals with ASD. The workshop will be open to the public, will include time for public comments, and will be accessible by live webcast and conference call.

Name of Committee: Interagency Autism Coordinating Committee (IACC).

Type of meeting: 2019 IACC Workshop on Addressing the Health Outcome Needs of People with Autism Spectrum Disorder.

Date: Tuesday, May 21, 2019.

Time: 8:30 a.m. to 5:00 p.m. Eastern Time.

Agenda: The workshop will focus the discussion on the health and wellness of individuals with Autism Spectrum Disorder, including health epidemiology, patient-provider interaction, and the state of the science on commonly co-occurring health conditions affecting individuals on the autism spectrum.

Place: Hilton Washington DC/Rockville Hotel and Executive Meeting Ctr, 1750 Rockville Pike, Rockville, MD 20852.

Webcast Live: https://videocast.nih.gov.

Conference Call: 800–369–3119.

Access code: 5777378.

Cost: The meeting is free and open to the public.

Registration: A registration web link will be posted on the IACC website (*www.iacc.hhs.gov*) prior to the meeting. Pre-registration is recommended to expedite check-in. Seating in the meeting room is limited to room capacity and on a first come, first served basis. Onsite registration will also be available.

Deadlines: Notification of intent to present oral comments: Friday, May 10, 2019, by 5:00 p.m. ET. Submission of written/electronic statement for oral comments: Tuesday, May 14, 2019, by 5:00 p.m. ET. Final deadline for submission of written comments: Tuesday, May 14, 2019, by 5:00 p.m. ET. Webcast Live Feedback Public comments: No preregistration required. For instructions, see *https://iacc.hhs.gov/meetings/iacc-meetings/live-feedback.shtml*. For IACC public comment guidelines, please see: *https://iacc.hhs.gov/meetings/public-comments/guidelines/*.

Access: Twinbrook Metro Station (Red Line).

Contact Person: Ms. Angelice Mitrakas, Office of Autism Research Coordination, National Institute of Mental Health, NIH, 6001 Executive Boulevard, Room 7218, Bethesda, MD 20892–9669, Phone: 301–435–9269, Email: *IACCPublicInquiries@mail.nih.gov*.

Public Comments: The IACC invites oral and written public-related comments relevant to the topic of the workshop. Individuals interested in presenting oral comments must notify the Contact Person listed on this notice by 5:00 p.m. ET on Friday, May 10, 2019, with their request to present oral comments at the meeting, and a written/electronic copy of the oral presentation/statement must be submitted by 5:00 p.m. ET on Tuesday, May 14, 2019.

A limited number of slots for oral comment are available and will be assigned on a first come, first serve basis. Only one representative of an organization will be allowed to present oral comments at this meeting; other representatives of the same group may provide written comments. If the oral comment session is full, individuals who could not be accommodated are welcome to provide written comments instead. Comments to be read or presented in the meeting will be assigned a 3-minute time slot, but a longer version may be submitted in writing for the record. Commenters going beyond their allotted time in the meeting may be asked to conclude immediately to allow other comments and presentations to proceed on schedule.

Any interested person may submit written public comments to the IACC prior to the meeting by emailing the comments to *IACCPublicInquiries@mail.nih.gov,* or by submitting comments at the web link: *https://iacc.hhs.gov/meetings/public-comments/submit/index.jsp* by 5:00 p.m. ET on Tuesday, May 14, 2019. The comments should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. NIMH anticipates written public comments received by 5:00 p.m. ET on Tuesday, May 14, 2019, will be presented to the working group prior to the workshop. Any written comments received after the by 5:00 p.m. ET on Tuesday, May 14, 2019 deadline through Monday, May 20, 2019, will be provided to the working group either before or after the meeting, depending on the volume of comments received and the time required to process them in accordance with privacy regulations and other applicable Federal policies. All written public comments and oral public comment statements received by the deadlines for both oral and written public comments will be provided to the IACC for their consideration and will become part of the public record. Attachments of copyrighted publications are not permitted, but web links or citations for any copyrighted works cited may be provided.

Individuals may also submit public comments to the IACC via a Live Feedback Form accessible from the webcast page on the day of the meeting from 9:00 a.m. ET to 11:00 a.m. ET. No pre-registration required. The link will be accessible on the NIH Videocast website and instructions are available on the IACC website: *https://iacc.hhs.gov/meetings/iacc-meetings/live-feedback.shtml* This format is best suited for brief questions and comments for the IACC. Submissions will be provided to the IACC and will become a part of the public record.

In the 2009 IACC Strategic Plan, the IACC listed the ''Spirit of Collaboration'' as one of its core values, stating that, ''We will treat others with respect, listen to diverse views with open minds, discuss submitted public comments, and foster discussions where participants can comfortably offer opposing opinions.'' In keeping with this core value, the IACC and the NIMH Office of Autism Research Coordination (OARC) ask that members of the public who provide public comments or participate in meetings of the IACC also seek to treat others with respect and consideration in their communications and actions, even when discussing issues of genuine concern or disagreement.

Remote Access: The meeting will be open to the public through a conference call phone number and webcast live on