

Respondents to this collection of information are manufacturers and repackagers of male condoms made of natural rubber latex without spermicidal lubricant. FDA expects approximately five new manufacturers or repackagers to enter the market yearly and to collectively have a third-party disclosure burden of 60 hours. The average burden per disclosure was derived from a study performed for FDA by Eastern Research Group, Inc., an economic consulting firm, to estimate the impact of the 1999 over-the-counter (OTC) human drug labeling

requirements final rule (64 FR 13254, March 17, 1999). Because the packaging requirements for condoms are similar to those of many OTC drugs, we believe the burden to design the labeling for OTC drugs is an appropriate proxy for the estimated burden to design condom labeling.

The special controls guidance document also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR

part 807, subpart E have been approved under OMB control number 0910-0120; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073.

The collection of information under 21 CFR 801.437 does not constitute a “collection of information” under the PRA. Rather, it is a “public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public” (5 CFR 1320.3(c)(2)).

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

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
“Class II Special Controls Guidance Document: Labeling for Natural Rubber Latex Condoms Classified Under 21 CFR 884.5300” .....	5	1	5	12	60

<sup>1</sup> 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: December 29, 2020.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Toxicology Program Board of Scientific Counselors; Announcement of Meeting; Request for Comments**

**AGENCY:** National Institutes of Health, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the next meeting of the National Toxicology Program (NTP) Board of Scientific Counselors (BSC). The BSC, a federally chartered, external advisory group composed of scientists from the public and private sectors, will review and provide advice on programmatic activities. This meeting is a virtual meeting and is open to the public. Written comments will be accepted and registration is required to present oral comments. Information about the meeting and registration is available at <https://ntp.niehs.nih.gov/go/165>.

**DATES:**

**Meeting:** Scheduled for February 2, 2021, 12:30 p.m.–5:00 p.m. Eastern Standard Time (EST). Written Public Comment Submissions: Deadline is January 26, 2021.

**Registration for Oral Comments:** Deadline is January 26, 2021.

**ADDRESSES:**

**Meeting Web page:** The preliminary agenda, registration, and other meeting materials are available at <https://ntp.niehs.nih.gov/go/165>.

**Virtual Meeting:** The URL for viewing the virtual meeting will be provided on the meeting web page.

**FOR FURTHER INFORMATION CONTACT:** Dr. Sheena Scruggs, Designated Federal Official for the BSC, Office of Liaison, Policy and Review, Division of NTP, NIEHS, P.O. Box 12233, K2-03, Research Triangle Park, NC 27709. Phone: 984-287-3355, Fax: 301-451-5759, Email: [sheena.scruggs@nih.gov](mailto:sheena.scruggs@nih.gov). Hand Deliver/Courier address: 530 Davis Drive, Room K2130, Morrisville, NC 27560.

**SUPPLEMENTARY INFORMATION:** The BSC will provide input to the NTP on programmatic activities and issues. The preliminary agenda topics include presentations from two of the Division of the National Toxicology Program (DNTP)’s research program areas. The preliminary agenda, roster of BSC members, background materials, public comments, and any additional information, when available, will be posted on the BSC meeting web page (<https://ntp.niehs.nih.gov/go/165>) or may be requested in hardcopy from the

Designated Federal Official for the BSC. Following the meeting, summary minutes will be prepared and made available on the BSC meeting web page.

**Meeting Attendance Registration:** The meeting is open to the public with time scheduled for oral public comments. Registration is not required to view the virtual meeting; the URL for the virtual meeting is provided on the BSC meeting web page (<https://ntp.niehs.nih.gov/go/165>). TTY users should contact the Federal TTY Relay Service at 800-877-8339. Requests should be made at least five business days in advance of the event.

**Written Public Comments:** NTP invites written public comments. Guidelines for public comments are available at [https://ntp.niehs.nih.gov/ntp/about\\_ntp/guidelines\\_public\\_comments\\_508.pdf](https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf).

The deadline for submission of written comments is January 26, 2021. Written public comments should be submitted through the meeting web page. Persons submitting written comments should include name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP web page, and the submitter will be identified by name, affiliation, and sponsoring organization (if any).

**Oral Public Comment Registration:** The agenda allows for two formal public comment periods—one comment period for each program area (up to 3 commenters, up to 5 minutes per speaker, per topic). Persons wishing to

make an oral comment are required to register online at <https://ntp.niehs.nih.gov/go/165> by January 26, 2021. Oral comments will be received only during the formal comment periods indicated on the preliminary agenda. Oral comments will only be by teleconference line. The access number for the teleconference line will be provided to registrants by email prior to the meeting. Registration is on a first-come, first-served basis. Each organization is allowed one time slot per topic. After the maximum number of speakers per comment period is exceeded, individuals registered to provide oral comment will be placed on a wait list and notified should an opening become available. Commenters will be notified approximately one week before the meeting about the actual time allotted per speaker.

If possible, oral public commenters should send a copy of their slides and/or statement or talking points to [NTP-Meetings@icf.com](mailto:NTP-Meetings@icf.com) by January 26, 2021.

**Meeting Materials:** The preliminary meeting agenda is available on the meeting web page (<https://ntp.niehs.nih.gov/go/165>) and will be updated one week before the meeting. Individuals are encouraged to access the meeting web page to stay abreast of the most current information regarding the meeting.

**Background Information on the BSC:** The BSC is a technical advisory body comprised of scientists from the public and private sectors that provides primary scientific oversight to the NTP. Specifically, the BSC advises the NTP on matters of scientific program content, both present and future, and conducts periodic review of the program for the purpose of determining and advising on the scientific merit of its activities and their overall scientific quality. Its members are selected from recognized authorities knowledgeable in fields such as toxicology, pharmacology, pathology, epidemiology, risk assessment, carcinogenesis, mutagenesis, cellular biology, computational toxicology, neurotoxicology, genetic toxicology, reproductive toxicology or teratology, and biostatistics. Members serve overlapping terms of up to four years. The BSC usually meets periodically. The authority for the BSC is provided by 42 U.S.C. 217a, section 222 of the Public Health Service Act (PHS), as amended.

The BSC is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. app.), which sets forth standards for the formation and use of advisory committees.

Dated: December 29, 2020.

**Brian R. Berridge,**

*Associate Director, National Toxicology Program.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine and Oral Fluid Drug Testing for Federal Agencies

**AGENCY:** Substance Abuse and Mental Health Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine or Oral Fluid (Mandatory Guidelines).

**FOR FURTHER INFORMATION CONTACT:** Anastasia Donovan, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N06B, Rockville, Maryland 20857; 240-276-2600 (voice); [Anastasia.Donovan@samhsa.hhs.gov](mailto:Anastasia.Donovan@samhsa.hhs.gov) (email).

**SUPPLEMENTARY INFORMATION:** A notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at <https://www.samhsa.gov/workplace/resources/drug-testing/certified-lab-list>.

The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and

of the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

The Mandatory Guidelines using Urine were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); April 30, 2010 (75 FR 22809); and on January 23, 2017 (82 FR 7920).

The Mandatory Guidelines using Oral Fluid were first published in the **Federal Register** on October 25, 2019 (84 FR 57554) with an effective date of January 1, 2020.

The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100-71 and allowed urine drug testing only. The Mandatory Guidelines using Urine have since been revised, and new Mandatory Guidelines allowing for oral fluid drug testing have been published. The Mandatory Guidelines require strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on specimens for federal agencies. HHS does not allow IITFs to conduct oral fluid testing.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines using Urine and/or Oral Fluid. An HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that the test facility has met minimum standards. HHS does not allow IITFs to conduct oral fluid testing.

#### HHS-Certified Laboratories Approved To Conduct Oral Fluid Drug Testing

In accordance with the Mandatory Guidelines using Oral Fluid dated October 25, 2019 (84 FR 57554), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on oral fluid specimens:

At this time, there are no laboratories certified to conduct drug and specimen validity tests on oral fluid specimens.