TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					26,020

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

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
208.24(c)	191	9,000	1,719,000	1.25	2,148,750
Distributing and Dispensing a Medication Guide—208.24(e)	88,736	5,000	443,680,000	0.05 (3 minutes).	22,184,000
Total					24,332,750

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

Dated: May 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12976 Filed 5–28–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1081]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled, ''Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: On January 8, 2015, the Agency submitted a proposed collection of information entitled, ''Guidance for Industry on Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During an Influenza Pandemic'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0701. The approval expires on April 30, 2018. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain*.

Dated: May 22, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12977 Filed 5–28–15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Mandatory Guidelines for Federal Workplace Drug Testing Programs; Request for Information Regarding Specific Issues Related to the Use of the Hair Specimen for Drug Testing

AGENCY: Substance Abuse and Mental Health Services Administration (SAMHSA), Department of Health and Human Services (DHHS).

ACTION: Request for Information.

SUMMARY: This document is a request for information regarding specific aspects of the regulatory policies and standards that may be applied to the Mandatory Guidelines for Federal Workplace Drug Testing Programs (hair specimen).

DATES: *Comment Close Date:* To be assured consideration, comments must be received at one of the addresses provided below on or before June 29, 2015.

ADDRESSES: Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of four ways (please choose only one of the ways listed):

Electronically: You may submit electronic comments to *http://www.regulations.gov*. Follow ''Submit a comment'' instructions.

By regular mail: You may mail written comments to the following address only: Substance Abuse and Mental Health Services Administration, Attention: Division of Workplace Programs, 1 Choke Cherry Road, Room 7–1029, Rockville, MD 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.

By express or overnight mail: You may send written comments to the following address only: Substance Abuse and Mental Health Services Administration, Attention: Division of Workplace Programs, 1 Choke Cherry Road, Room 7–1029, Rockville, MD 20850.

By hand or courier: Alternatively, you may deliver (by hand or courier) your written comments only to the following address prior to the close of the comment period:

For delivery in Rockville, MD: Substance Abuse and Mental Health Services Administration, Attention: Division of Workplace Programs, 1 Choke Cherry Road, Room 7–1029, Rockville, MD 20850. To deliver your

comments to the Rockville address, call telephone number (240) 276–2600 in advance to schedule your delivery with one of our staff members. Because access to the interior of the Substance Abuse and Mental Health Services Administration Building is not readily available to persons without federal government identification, commenters are encouraged to either schedule your drop off or leave your comments with the security guard in the main lobby of the building.

FOR FURTHER INFORMATION CONTACT: Sean Belouin, Division of Workplace Programs, Center for Substance Abuse Prevention (CSAP), SAMHSA, 1 Choke Cherry Road, Room 7–1029, Rockville, Maryland 20857, (240) 276–2716 (phone), (240) 276–2610 (Fax), or email at *sean.belouin@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION: Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments. Comments received by the deadline will also be available for public inspection at the Substance Abuse and Mental Health Services Administration, Division of Workplace Programs, 1 Choke Cherry Road, Rockville, MD 20850, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (240) 276–2716.

I. Background

The Department of Health and Human Services (HHS) establishes the standards for Federal Workplace Drug Testing Programs under the authority of Section 503 of Public Law 100–71, 5 U.S.C. 7301, and Executive Order No. 12564. As required, HHS published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the **Federal Register** on April 11, 1988 [53 FR 11979]. SAMHSA subsequently revised the Guidelines on June 9, 1994 [59 FR 29908], September 30, 1997 [62 FR 51118], November 13, 1998 [63 FR 63483], April 13, 2004 [69 FR 19644], and on November 25, 2008 [73 FR 71858]. On May 15, 2015, HHS published a notice of proposed revisions to the mandatory guidelines which would provide federal executive branch agencies with the option of collecting and testing an oral fluid specimen in addition to urine specimen. The comment period concludes on July 14, 2015.

Section 503 of Public Law 100–71, 5 U.S.C. 7301 note, required the Department to establish scientific and technical guidelines and amendments in accordance with Executive Order 12564 and to publish Mandatory Guidelines which establish comprehensive standards for all aspects of laboratory drug testing and procedures, including standards that require the use of the best available technology for ensuring the full reliability and accuracy of drug tests and strict procedures governing the chain of custody of specimens collected for drug testing. These revisions to the Mandatory Guidelines promote and establish standards that use the best available technology for ensuring the full reliability and accuracy of drug tests, while reflecting the ongoing process of review and evaluation of legal, scientific, and societal concerns.

SAMHSA's chartered CSAP Drug Testing Advisory Board (DTAB) is the vehicle to provide recommendations to the SAMHSA Administrator for proposed changes to the Mandatory Guidelines for Federal Workplace Drug Testing Programs. The DTAB process involves evaluating the scientific supportability of any considered change. To assist the DTAB, we are soliciting written comments and statements from the general public and industry stakeholders regarding a variety of issues related to hair specimen drug testing, including the hair specimen, its collection, specimen preparation, analytes/cutoffs, specimen validity, and initial and confirmatory testing.

II. Solicitation of Comments

We are seeking additional information to inform potential use of hair specimens for drug testing, specifically on the following questions:

Hair Specimen:

- What are the acceptable body locations from which to collect hair for workplace drug testing? What should be done if head hair is not available for collection?
- What hair treatments (*i.e.,* shampoo, conditioning, perm, relaxers, coloring, bleaching, straightening, hair transplant) influence drug concentration in hair and to what degree?
- What are the acceptable reasons for hair testing (*i.e.,* pre-employment, random, reasonable suspicion, post-accident, other (fitness for duty, return to duty, etc.))?

Collection:

- What training should a collector receive prior to collecting the hair specimen?
- What is the best protocol to collect the hair specimen?
- Should the hair collection protocol be standardized, including specific instructions on how close to cut the hair specimen to the skin, how to determine the authenticity of the hair specimen, what cutting instruments to use, how to ensure the cutting instruments are decontaminated, and whether the use of collection kits should be required?
- What is the minimum amount of hair that should be collected?

Specimen Preparation:

- What are acceptable protocols for hair specimen preparation, such as cutting/powdering, initial washing, decontamination, and pre-extraction (*i.e.,* digestion, micro pulverization, etc.)?
- Should the washing and decontamination procedures be analyte specific?
- What criteria should be used to determine the acceptability of a specific wash and decontamination procedure? Are there published research studies, with experimental data included, that demonstrate that a particular wash procedure is effective at removing external contaminants while not significantly affecting the amount of incorporated drug related to drug use?
- If washing steps are used for decontamination, should adjustments be made for drug concentrations detected in the wash fluids? What calculations are recommended for these adjustments?

Analytes/Cutoffs:

- What analytes should be measured in hair by the initial and confirmatory tests?
- What initial and confirmation cutoffs should be used for the various hair drug testing analytes?
- For each analyte/drug, what criteria (cutoff) should be used to distinguish external contamination from drug use?
- What unique metabolites or other biomarkers exist to confirm use and to distinguish drug use from external contamination for which the drugs are currently tested?

Specimen Validity:

- Are biomarkers or tests needed to verify that the specimen is authentic human hair?
- Are there appropriate biomarkers or tests for the hair specimen that would reveal adulteration and/or substitution? What are the acceptability criteria for these biomarkers or tests?
- Is the ''invalid'' result category reasonable for hair testing? If so, what criteria are acceptable to classify a specimen result as invalid?

Testing:

- What technologies are available to perform initial and confirmatory testing on hair specimens?
- What is the best sample for valid quality control/proficiency testing material? How should this quality control/proficiency testing material be prepared? What is the best method to prepare a contaminated hair sample versus a sample that represents drug use?

Janine Cook,

Chemist, Division of Workplace Programs, Center for Substance Abuse and Prevention, SAMHSA.

[FR Doc. 2015–12743 Filed 5–28–15; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2015–0455]

Certificates of Alternative Compliance

AGENCY: Coast Guard, DHS.

ACTION: Notice.

SUMMARY: The Coast Guard announces that the Coast Guard District Prevention Divisions have issued certificates of alternative compliance to vessels of special construction or purpose that cannot fully comply with the light, shape, and sound signal provisions of the International Regulations for Preventing Collisions at Sea (72 COLREGS) and/or Inland Navigation Rules without interfering with their special function. This notice promotes the Coast Guard's maritime safety and stewardship missions.

FOR FURTHER INFORMATION CONTACT: For information about this document call or email LCDR Megan Cull, Coast Guard Navigation Standards Division; telephone (202) 372–1565, email *megan.l.cull@uscg.mil.* For information about viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826, toll free 1–800–647–5527.

SUPPLEMENTARY INFORMATION:

Discussion

The special construction or purpose of some vessels makes them unable to comply with the light, shape, and sound signal provisions of the 72 COLREGS and/or Inland Navigation Rules. Under 72 COLREGS, statutory law and Coast Guard regulations, a vessel may instead meet alternative requirements and the vessel's owner, builder, operator, or agent may apply for a certificate of alternative compliance (COAC). The Chief of the Inspections and Investigations Branch in each Coast Guard District office determines whether the vessel for which the COAC is sought complies as closely as possible with the 72 COLREGS and/or Inland Navigation Rules, and decides whether to issue the COAC. Once issued, a COAC remains valid until information supplied in the application for the COAC, or the terms of the COAC becomes inapplicable to the vessel. Under the governing statute [1] and regulation,[2] the Coast Guard must publish notice of each COAC.

The Coast Guard issued COACs to the following vessels between 2010 and 2014:

2010	ALLISON CROSBY	Sidelights on the outboard edges of the superstructure 6′ 8″ from the centerline. Restricted in ability to maneuver/not under command lights may be installed 1 foot below each masthead light on either side of mast.
2010	BEE HIVE	Forward masthead light 38′ 2¼″ above main deck; aft masthead light 18′ 10$^{9}/_{16}$″ aft of forward masthead light; aft anchor light 25′ 1$^{5}/_{16}$″ off center to starboard side, just forward of the stern; sidelights on the side of the pilothouse 12′ 4¼″ inboard of the greatest breadth.
2010	BETTY PFANKUCH	Aft masthead light on the main mast above pilothouse, 20′ 5″ aft of the forward masthead light.
2010	BETTY PFANKUCH	Duplicate COAC with addition of allowing two 360° restricted in ability to maneuver/not under command lights on aft mast to allow 360° visibility.
2010	C–COURAGEOUS	Aft masthead light on the main mast above the pilothouse, 21′ 8¾″ aft of the forward masthead light.
2010	DWIGHT S. RAMSAY ...	Aft masthead light on the main mast above the pilothouse, 20′ 5″ aft of the forward masthead light. Two 360° restricted in ability to maneuver/not under command lights on aft mast to allow 360° visibility.
2010	FAST GIANT	Forward masthead light above the pilothouse 18.92′ above the hull, and its aft masthead light on the main mast above the pilothouse, 16.83′ aft and 14.76′ above the forward masthead light.
2010	FAST TITAN	Forward masthead light above the pilothouse 18.92′ above the hull, and its aft masthead light on the main mast above the pilothouse, 16.83′ aft and 14.76′ above the forward masthead light.
2010	JOHN W. JOHNSON	Aft masthead lights on the main mast atop of each pilothouse 115″ aft of each forward masthead light located atop the opposing pilothouse. Sidelights located on the side of the pilothouse.
2010	KELLIE CHOUEST	Aft masthead light on main mast above pilothouse, 25′ 5$^{5}/_{16}$″ aft of forward masthead light; sidelights 15′ 8″ inboard from greatest breadth; two sets of 360° restricted in ability to maneuver/not under command lights on the aft mast, one set on each side of the mast, 1′ 1″ from the centerline.
2010	M/V ANNA G	Sidelights on the top of the pilothouse, 8′ 1″ inboard from the greatest breadth of the vessel.
2010	M/V CHARLEVOIX	Reduce the intensity of the required sound signal to 85 decibel when leaving the dock/berth during normal operations.
2010	M/V JODY MCMINN	Sidelights placed forward of the masthead light and located on the outermost edge of the pilothouse more than 10% inboard of the greatest breadth of the vessel.
2010	M/V JOE GRIFFIN	Aft masthead light on the main mast above the pilothouse, 21′ 10″ aft of the forward masthead light.
2010	M/V NICHOLAS P CALLAIS.	Aft masthead light on the main mast above the pilothouse, 24′ 4″ aft of the forward masthead light.
2010	M/V QUEEN BEE	Forward masthead light on top of the pilothouse 38′ 2¼″ above main deck and aft masthead light on main mast above pilothouse, 18′ 10$^{9}/_{16}$″ aft of the forward masthead light, and its aft anchor light 25′ 1$^{5}/_{16}$″ off center to the starboard side, just forward of the stern. In addition, the sidelights may be placed on the side of the pilothouse 12′ 4½″ inboard of the greatest breadth of the vessel.
2010	M/V RAYMOND C. PERCOR, JR.	Single Voyage COAC horizontal separation between forward and aft masthead light, 84′. Height of forward masthead light, 29′ 10″. Vertical separation of forward and aft masthead light, 6′ 11″. Sidelights placed 26′ 4″ above main deck. Vertical separation between sidelights and forward masthead light 3′ 6″. Sidelights placed on outside edge of pilothouse symmetric about the axis line of the masthead lights.

[1] 33 U.S.C. 1605(c).

[2] 33 CFR 81.18.