TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN 1—Continued

<table>
<thead>
<tr>
<th>21 CFR Section</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
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<tbody>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
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<td>26,020</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>21 CFR Section</th>
<th>Number of respondents</th>
<th>Number of disclosures per respondent</th>
<th>Total annual disclosures</th>
<th>Average burden per disclosure</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>208.24(c)</td>
<td></td>
<td>191</td>
<td>9,000</td>
<td>1,719,000</td>
<td>2,148,750</td>
</tr>
<tr>
<td>Distributing</td>
<td></td>
<td>88,736</td>
<td>5,000</td>
<td>443,680,000</td>
<td>22,184,000</td>
</tr>
<tr>
<td>and Dispensing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>a Medication</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Guide—208.24(e)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>24,332,750</td>
</tr>
</tbody>
</table>

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]
BILLING CODE 4164–01–P

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):


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.

When sending by hand or courier, comments must be addressed 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.
SUPPLEMENTARY INFORMATION:

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. (Phone) (240) 276–2610, (Fax) (240) 276–2610, or email 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


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, analyte/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 is the best protocol for collecting the hair specimen? 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?
• Are there appropriate 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?

Collection:

• 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?

• Are there appropriate 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?

Are 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]
BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

Certificate of Alternative Compliance

[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 (COAC) 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 viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, 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) 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) 372–1565, email megan.l.cull@uscg.mil.

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 and regulation, the Coast Guard must publish notice of each COAC.

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

<table>
<thead>
<tr>
<th>Year</th>
<th>Vessel Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>ALLISON CROSBY</td>
<td>Sidelongts on the outboard edges of the superstructure 6' 8&quot; 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.</td>
</tr>
<tr>
<td>2010</td>
<td>BEE HIVE</td>
<td>Forward masthead light 38' 2 1/4&quot; above main deck; aft masthead light 18' 10 1/4&quot; aft of forward masthead light; aft anchor light 25' 1 1/4&quot; off center to starboard side, just forward of the stem; sidelights on the side of the pilothouse 12' 4 1/4&quot; inboard of the greatest breadth.</td>
</tr>
<tr>
<td>2010</td>
<td>BETTY PFANKUCH</td>
<td>Aft masthead light on the main mast above pilothouse, 20' 5&quot; aft of forward masthead light.</td>
</tr>
<tr>
<td>2010</td>
<td>BETTY PFANKUCH</td>
<td>Duplicate COAC with addition of allowing two 360° restricted in ability to maneuver/not under command lights on aft mast to allow 360° visibility.</td>
</tr>
<tr>
<td>2010</td>
<td>DWIGHT S. RAMSAy</td>
<td>Forward masthead light on the main mast above pilothouse, 20' 5&quot; aft of the forward masthead light. Two 360° restricted in ability to maneuver/not under command lights on aft mast to allow 360° visibility.</td>
</tr>
<tr>
<td>2010</td>
<td>FAST GIANT</td>
<td>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.</td>
</tr>
<tr>
<td>2010</td>
<td>FAST TITAN</td>
<td>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.</td>
</tr>
<tr>
<td>2010</td>
<td>JOHN W. JOHNSON</td>
<td>Aft masthead light 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.</td>
</tr>
<tr>
<td>2010</td>
<td>KELLIE CHOUEST</td>
<td>Aft masthead light on main mast above pilothouse, 25' 5 1/4&quot; aft of forward masthead light; sidelights 15' 8&quot; 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&quot; from the centerline.</td>
</tr>
<tr>
<td>2010</td>
<td>M/V ANNA G</td>
<td>Sidelights on the top of the pilothouse, 8' 1&quot; inboard from the greatest breadth of the vessel.</td>
</tr>
<tr>
<td>2010</td>
<td>M/V CHARLEVOIX</td>
<td>Reduce the intensity of the required sound signal to 85 decibel when leaving the dock/berth during normal operations.</td>
</tr>
<tr>
<td>2010</td>
<td>M/V JODY MCMINN</td>
<td>Sidelights placed forward of the masthead light and located on the outmost edge of the pilothouse more than 10% inboard of the greatest breadth of the vessel.</td>
</tr>
<tr>
<td>2010</td>
<td>M/V JOE GRIFFIN</td>
<td>Aft masthead light on the main mast above the pilothouse, 21' 10&quot; aft of the forward masthead light.</td>
</tr>
<tr>
<td>2010</td>
<td>M/V NICHOLAS P CALLAIS</td>
<td>Aft masthead light on the main mast above the pilothouse, 24' 4&quot; aft of the forward masthead light.</td>
</tr>
<tr>
<td>2010</td>
<td>M/V QUEEN BEE</td>
<td>Forward masthead light on top of the pilothouse 38' 2 1/4&quot; above main deck and aft masthead light on main mast above pilothouse, 18' 10 1/4&quot; aft of the forward masthead light, and its aft anchor light 25' 1 1/4&quot; off center to the starboard side, just forward of the stem. In addition, the sidelights may be placed on the side of the pilothouse 12' 4 1/2&quot; inboard of the greatest breadth of the vessel.</td>
</tr>
<tr>
<td>2010</td>
<td>M/V RAYMOND C. PERC nond.</td>
<td>Single Voyage COAC horizontal separation between forward and aft masthead light, 84'. Height of forward masthead light, 29' 10&quot;. Vertical separation of forward and aft masthead light, 6' 11&quot;. Sidelights placed 26' 4&quot; above main deck. Vertical separation between sidelights and forward masthead light 3' 6&quot;. Sidelights placed on outside edge of pilothouse symmetric about the axis line of the masthead lights.</td>
</tr>
</tbody>
</table>

1 33 U.S.C. 1605(c).
2 33 CFR 81.18.