

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.

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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.

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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