*2. Notification of Results of Tests and Investigations Regarding or Possibly Impacting the Product*

In the guidance, we recommend the following for contract manufacturing arrangements:

- The contract manufacturer should fully inform the license manufacturer of the results of all tests and investigations regarding or possibly having an impact on the product; and
- The license manufacturer should obtain assurance from the contractor that any FDA list of inspectional observations will be shared with the license manufacturer to allow evaluation of its impact on the purity, potency, and safety of the license manufacturer's product.

*3. Notification of Products Manufactured in a Contract Facility*

In the guidance, we recommend for contract manufacturing arrangements that a license manufacturer cross reference a contract manufacturing facility's master files only in circumstances involving certain proprietary information of the contract manufacturer, such as a list of all products manufactured in a contract facility. In this situation, the license manufacturer should be kept informed of the types or categories of all products manufactured in the contract facility.

*4. Standard Operating Procedures*

In the guidance, we remind the license manufacturer that the license manufacturer assumes responsibility for compliance with the applicable product and establishment standards (21 CFR 600.3(t)). Therefore, if the license manufacturer enters into an agreement with a contract manufacturing facility, the license manufacturer must ensure that the facility complies with the applicable standards. An agreement between a license manufacturer and a contract manufacturing facility normally includes procedures to regularly assess the contract manufacturing facility's compliance. These procedures may include, but are not limited to, review of records and manufacturing deviations and defects, and periodic audits.

For shared manufacturing arrangements, each manufacturer must submit a separate biologics license application describing the manufacturing facilities and operations applicable to the preparation of that manufacturer's biological substance or product (§ 601.2(a)). In the guidance, we state that we expect the manufacturer that prepares, or is responsible for the preparation of, the product in final form for commercial distribution to assume primary responsibility for providing data demonstrating the safety, purity, and potency of the final product. We also state that we expect the licensed finished product manufacturer to be primarily responsible for any postapproval obligations, such as postmarketing clinical trials, additional product stability studies, complaint handling, recalls, postmarket reporting of the dissemination of advertising and promotional labeling materials as required under § 601.12(f)(4), and adverse experience reporting. We recommend that the final product manufacturer establish a procedure with the other participating manufacturer(s) to obtain information in these areas.

*Description of Respondents:* Respondents to the information collection are participating licensed manufacturers, final product manufacturers, and contract manufacturers associated with cooperative manufacturing arrangements subject to the associated regulations discussed in the guidance.

*Burden Estimate:* We believe that the information collection provisions in the guidance do not create a new burden for respondents. We believe the reporting and recordkeeping provisions are part of usual and customary business practices. Licensed manufacturers would have contractual agreements with participating licensed manufacturers, final product manufacturers, and contract manufacturers, as applicable for the type of cooperative manufacturing arrangement, to address all these information collection provisions.

The guidance also refers to previously approved collections of information found in FDA regulations at parts 201, 207, 211, 600, 601, 606, 607, 610, 660, 801, 803, 807, 809, and 820 (21 CFR parts 201, 207, 211, 600, 601, 606, 607, 610, 660, 801, 803, 807, 809, and 820). The collections of information in parts 606 and 610 have been approved under OMB control numbers 0910–0116, 0910–0458, and 0910–0206; part 600 has been approved under OMB control numbers 0910–0308 and 0910–0458; parts 601 and 660 have been approved under OMB control number 0910–0338; part 803 has been approved under OMB control number 0910–0437; part 211 has been approved under OMB control number 0910–0139; part 820 has been approved under OMB control number 0910–0073; parts 207, 607, and 807 have been approved under OMB control numbers 0910–0045, 0910–0052, and 0910–0625; and parts 201, 801, and 809 have been approved under OMB control numbers 0910–0537, 0910–0572, and 0910–0485.

Dated: August 2, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017–16564 Filed 8–4–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2010–N–0110]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug Advertisements

**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 September 6, 2017.

**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 0910–0686. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Prescription Drug Advertisements (OMB Control Number 0910–0686—Extension)

This information collection supports Agency regulations. Section 502(n) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 352(n)) requires that manufacturers, packers, and distributors (sponsors) who

advertise prescription human and animal drugs, including biological products for humans, disclose in advertisements certain information about the advertised product's uses and risks. For prescription drugs and biologics, section 502(n) of the FD&C Act requires advertisements to contain ''a true statement . . .'' of certain information including ''. . . information in brief summary relating to side effects, contraindications, and effectiveness . . .'' as required by regulations issued by FDA.

FDA's prescription drug advertising regulations at § 202.1 (21 CFR 202.1) describe requirements and standards for print and broadcast advertisements. Section 202.1 applies to advertisements published in journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems. Print advertisements must include a brief summary of each of the risk concepts from the product's approved package labeling (§ 202.1(e)(1)). Advertisements that are broadcast through media such as television, radio, or telephone communications systems must disclose the major risks from the product's package labeling in either the audio or audio and visual parts of the presentation (§ 202.1(e)(1)); this disclosure is known as the ''major statement.'' If a broadcast advertisement omits the major statement, or if the major statement minimizes the risks associated with the use of the drug, the advertisement could render the drug misbranded in violation of section 502(n) of the FD&C Act, section 201(n) of the FD&C Act (21 U.S.C. 321(n)), and FDA's implementing regulations at § 202.1(e).

Advertisements subject to the requirements at § 202.1 are subject to the PRA because these advertisements disclose information to the public. In addition, § 202.1(e)(6) and (j) include provisions that are subject to OMB approval under the PRA.

*Reporting to FDA*

Section 202.1(e)(6) permits a person who would be adversely affected by the enforcement of a provision of § 202.1(e)(6) to request a waiver from FDA for that provision. The waiver request must set forth clearly and concisely the petitioner's interest in the advertisement, the specific provision of § 202.1(e)(6) from which a waiver is sought, a complete copy of the advertisement, and a showing that the advertisement is not false, lacking in fair balance, misleading, or otherwise violative of section 502(n) of the FD&C Act.

Section 202.1(j), which sets forth requirements for the dissemination of advertisements subject to the standards in § 202.1(e), contains the following information collection that is subject to the PRA:

Under § 202.1(j)(1), a sponsor must submit advertisements to FDA for prior approval before dissemination if: (1) The sponsor or FDA has received information that has not been widely publicized in medical literature that the use of the drug may cause fatalities or serious damage; (2) FDA has notified the sponsor that the information must be part of the advertisements for the drug; and (3) the sponsor has failed to present to FDA a program for assuring that such information will be publicized promptly and adequately to the medical profession in subsequent advertisements, or if such a program has been presented to FDA but is not being followed by the sponsor.

Under § 202.1(j)(1)(iii), a sponsor must provide to FDA a program for assuring that significant new adverse information about the drug that becomes known (*i.e.,* use of drug may cause fatalities or serious damage) will be publicized promptly and adequately to the medical profession in any subsequent advertisements.

Under § 202.1(j)(4), a sponsor may voluntarily submit advertisements to FDA for comment prior to publication.

*Disclosures to the Public*

Under § 202.1, advertisements for human and animal prescription drug and biological products must comply with the standards described in that section.

Under § 202.1(j)(1), if information that the use of a prescription drug may cause fatalities or serious damage has not been widely publicized in the medical literature, a sponsor must include such information in the advertisements for that drug.

In the **Federal Register** of May 23, 2017 (82 FR 23574), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. One comment was received but did not respond to the information collection topics solicited in the notice and therefore we do not discuss it here.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR section or activity | Number of respondents | Number of responses per respondent | Total annual responses | Hours per response | Total hours |
|---|---|---|---|---|---|
| CDER | | | | | |
| 202.1(e)(6); waiver request | 1 | 1 | 1 | 12 | 12 |
| 202.1(j)(1); submission of advertisement | 1 | 1 | 1 | 2 | 2 |
| 202.1(j)(1)(iii); assuring that adverse information be publicized | 1 | 1 | 1 | 12 | 12 |
| 202.1(j)(4); voluntary submission of ad to FDA | 71 | 6.97 | 495 | 20 | 9,900 |
| CBER | | | | | |
| 202.1(e)(6); waiver request | 0 | 0 | 0 | 12 | 0 |
| 202.1(j)(1); submission of advertisement | 0 | 0 | 0 | 2 | 0 |
| 202.1(j)(1)(iii); assuring that adverse information be publicized | 0 | 0 | 0 | 12 | 0 |
| 202.1(j)(4); voluntary submission of ad to FDA | 9 | 8 | 72 | 20 | 1,440 |
| CVM | | | | | |
| 202.1(e)(6); waiver request | 0 | 0 | 0 | 12 | 0 |
| 202.1(j)(1); submission of advertisement | 0 | 0 | 0 | 2 | 0 |

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

| 21 CFR section or activity | Number of respondents | Number of responses per respondent | Total annual responses | Hours per response | Total hours |
|---|---|---|---|---|---|
| 202.1(j)(1)(iii); assuring that adverse information be publicized | 0 | 0 | 0 | 12 | 0 |
| 202.1(j)(4); voluntary submission of ad to FDA | 5 | 1 | 5 | 20 | 100 |
| Total | | | | | 11,466 |

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

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

| 21 CFR section or activity | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure | Total hours |
|---|---|---|---|---|---|
| CDER | | | | | |
| 202.1; ad prepared in accordance with part 202 | 394 | 105.3 | 41,494 | 400 | 16,597,600 |
| 202.1(j)(1); info. included re. fatalities or serious damage | 1 | 1 | 1 | 40 | 40 |
| CBER | | | | | |
| 202.1; ad prepared in accordance with part 202 | 47 | 63.4 | 2,984 | 400 | 1,193,600 |
| 202.1(j)(1); info. included re. fatalities or serious damage | 0 | 0 | 0 | 40 | 0 |
| CVM | | | | | |
| 202.1; ad prepared in accordance with part 202 | 25 | 36 | 900 | 400 | 360,000 |
| 202.1(j)(1); info. included re. fatalities or serious damage | 0 | 0 | 0 | 40 | 0 |
| Total | | | | | 18,151,240 |

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

Dated: August 2, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

[FR Doc. 2017–16607 Filed 8–4–17; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

### Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: AIDS Drug Assistance Program Data Report, OMB No. 0915–0345—Extension

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

**DATES:** Comments on this ICR should be received no later than September 6, 2017.

**ADDRESSES:** Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

**FOR FURTHER INFORMATION CONTACT:** To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

*Information Collection Request Title:* AIDS Drug Assistance Program Data Report OMB No. 0915–0345—Extension.

*Abstract:* HRSA's AIDS Drug Assistance Program (ADAP) is funded through the Ryan White HIV/AIDS Program (RWHAP), Part B, Title XXVI of the Public Health Service Act, which provides grants to states and territories. The ADAP provides medications for the treatment of HIV. Program funds may also be used to purchase health insurance for eligible clients and for services that enhance access, adherence, and monitoring of HIV drug treatments. The following states, territories, and Pacific Island jurisdictions are eligible to apply for RWHAP ADAP funding: All 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, the Republic of Palau, the Federated States of Micronesia, and the Republic of the Marshall Islands. As part of the funding requirements, ADAP grant recipients submit reports concerning information on patients served, eligibility requirements, pharmaceuticals prescribed, pricing and other sources of support to provide HIV medication treatment, cost data, and coordination with Medicaid. The ADAP Data Report (ADR) will be submitted