under the accommodation described previously, through an adjustment in the Federally-facilitated Exchange (FFE) user fee payable by an issuer participating in an FFE.

In order to facilitate the FFE user fee adjustment, and ensure that these user fee adjustments reflect payments for contraceptive services provided under this accommodation and that the adjustment is applied to the appropriate participating issuer in an FFE, the final rule requires an information collection from applicable participating issuers and third party administrators. In particular, the final regulations at 45 CFR 156.50(d)(2)(i) provide that a participating issuer who seeks an FFE user fee adjustment must submit to HHS in the year following the benefit year in which payments for contraceptive services were made under the previously mentioned accommodation, identifying information for the participating issuer, each third party administrator, and each self-insured group health plan, as well as the total dollar amount of the payments for contraceptive services that were provided during the applicable calendar year under the accommodation. The final regulation at 45 CFR 156.50(d)(2)(iii) also requires the third party administrator to submit to HHS identifying information for the third party administrator, the participating issuer, and each self-insured group health plan, as well as the total number of participants and beneficiaries in each self-insured group health plan during the applicable calendar year, the total dollar amount of payments made for contraceptive services, and an attestation that the payments for contraceptive services were made in compliance with 26 CFR 54.9815–2713A(b)(2) or 29 CFR 2590.715–2713A(b)(2).

Furthermore, to determine the potential number of submissions provided by third party administrators and allow HHS to prepare to receive submissions in calendar year 2015, the final regulation at 45 CFR 156.50(d)(2)(ii) requires third party administrators to submit to HHS a notification that the third party administrator intends for a participating issuer to seek an FFE user fee adjustment, by the later of January 1, 2014, or the 60th calendar day following the date on which the third party administrator receives a copy of a self-certification from an eligible organization. Additionally, a health insurance issuer providing payments for contraceptive services for participants and beneficiaries in insured plans (or student enrollees and covered dependents in student health insurance coverage) of eligible organizations to provide a written notice to such plan participants and beneficiaries (or such student enrollees and covered dependents) informing them of the availability of such payments.

The burden associated with these processes includes the time for applicable participating issuers and third party administrators to submit identifying information and total payments made for contraceptive services in the prior calendar year, and for third party administrators to notify HHS of their intent to seek the user fee adjustment. HHS estimates 488 third party administrators, 48 QHP issuers, and 325 fully insured issuers of eligible organizations will submit this information. HHS anticipates that participating issuers in an FFE seeking a user fee adjustment and third party administrators with respect to which the FFE user fee adjustment is received will submit this information electronically. *Form Number:* CMS–10492 (OMB Control Number: 0938–NEW); *Frequency:* Once, Yearly. *Affected Public:* Private Sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 861; *Total Annual Responses:* 861 *Total Annual Hours:* 12,930. (For policy questions regarding this collection contact Jaya Ghildiyal at (301) 492–5149.)

Dated: September 24, 2014.

Martique Jones,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2014–23132 Filed 9–26–14; 8:45 am]

BILLING CODE 4120–01–U–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1409]

Agency Information Collection Activities; Proposed Collection; Comment Request; Records and Reports Concerning Experiences With Approved New Animal Drugs: Adverse Event Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on adverse event reporting by FDA on new animal drugs and product/manufacturing defects collected on paper forms.

DATES: Submit either electronic or written comments on the collection of information by November 28, 2014.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and

assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Records and Reports Concerning Experiences With Approved New Animal Drugs: Adverse Event Reports on Paper Forms FDA 1932, 1932a, and 2301—21 CFR 514.80; OMB Control Number 0910–0284—Extension

Section 512(l) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b(l) and 514.80 (21 CFR 514.80) of FDA regulations require applicants of approved new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) to report adverse drug experiences and product/manufacturing defects (see § 514.80)(b)). Additionally, Section 571(e)(3) of the FD&C Act (21 U.S.C. 360ccc(e)(3)) requires that applicants for conditional approval of new animal drugs (CNADAs) maintain adequate reports and records of adverse drug experiences and product/manufacturing defects as applicable under section 512(l) of the FD&C Act.

The continuous monitoring of approved NADAs, ANADAs, and CNADAs affords the primary means by which FDA obtains information regarding potential problems with the safety and efficacy of marketed approved new animal drugs as well as potential product/manufacturing problems. Post-approval marketing surveillance is important because data previously submitted to FDA may not be adequate as animal drug effects can change over time and less apparent effects may take years to manifest.

Under § 514.80(d), an applicant must report adverse drug experiences and product/manufacturing defects on Form FDA 1932, ''Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report.'' Periodic drug experience reports and special drug experience reports must be accompanied by a completed Form FDA 2301, ''Transmittal of Periodic Reports and Promotional Material for New Animal Drugs,'' (see § 514.80). Form FDA 1932a, ''Veterinary Adverse Drug Reaction, Lack of Effectiveness or Product Defect Report,'' allows for voluntary reporting of adverse drug experiences or product/manufacturing defects.

In 2010, electronic versions of Forms FDA 1932 and 1932a were incorporated into the FDA Safety Reporting Portal. This electronic system is used for collecting, submitting, and processing adverse event reports and other safety information for all FDA-regulated products. Burden for the electronic version of these forms is accounted for under OMB control number 0910–0645. This approval request accounts for the collection of information using existing paper Forms FDA 1932, 1932a, and 2301 and is currently approved under OMB control number 0910–0284. FDA estimates that, at this time, approximately 50 percent of the respondents utilize paper forms for submitting this information. We expect this number to decrease as more respondents make use of the FDA Safety Reporting Portal.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section or section of the FD&C Act	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
514.80(b)(1), 514.80(b)(2)(i) and (ii), 514.80(b)(3)	1932	22	81.05	1,783	1	1,783
Voluntary reporting FDA Form 1932a for the public	1932a	197	1	197	1	197
514.80(b)(4)	2301	200	8.11	1,622	16	25,952
514.80(b)(5)(i)	2301	200	0.57	114	2	228
514.80(b)(5)(ii)	2301	200	20.12	4,024	2	8,048
514.80(b)(5)(iii)	2301	190	0.1	20	2	40
Total Hours						36,248

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of record keepers	Number of records per record keeper	Total annual records	Average burden per record keeping	Total hours
514.80(e)	646	7.20	4651	14	65117

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

Dated: September 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23059 Filed 9–26–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0623]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Voluntary Cosmetic Registration Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Voluntary Cosmetic Registration Program'' 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 July 8, 2014, the Agency submitted a proposed collection of information entitled ''Voluntary Cosmetic Registration Program'' 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 0910–0027. The approval expires on August 31, 2017. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: September 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–23066 Filed 9–26–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0397]

Internet/Social Media Platforms With Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices; Draft Guidance for Industry; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice of availability of the draft guidance entitled ''Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices,'' published in the **Federal Register** of June 18, 2014. FDA is reopening the comment period in response to a request for additional time and to allow interested persons more time to submit comments.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments by October 29, 2014.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding human prescription drugs: Jean-Ah Kang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993, 301–796–1200.

Regarding prescription human biological products: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

Regarding animal prescription drugs: Dorothy McAdams, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9300.

Regarding medical devices for human use: Deborah Wolf, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3414, Silver Spring, MD 20993, 301–796–5732.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 18, 2014 (79 FR 34759), FDA announced the availability of a draft guidance for industry entitled ''Internet/Social Media Platforms with Character Space Limitations: Presenting Risk and Benefit Information for Prescription Drugs and Medical Devices.'' In that document, FDA requested comments on the draft guidance, which responds to (among other things) stakeholder requests for specific guidance. The draft guidance describes FDA's current thinking on how manufacturers, packers, and distributors of prescription human and animal drugs and medical devices for human use, including biological products, that choose to present benefit information should present both benefit and risk information within advertising and promotional labeling of their FDA-regulated medical products on electronic/digital platforms that are associated with character space limitations, specifically on the Internet and through social media or other technological venues. The draft guidance represents FDA's current thinking on specific aspects of FDA's evolving consideration of social media platforms and other Internet-related matters. FDA actively continues to review, analyze, and develop approaches to a variety of topics related to the labeling and advertising of medical products, including the development of this and other guidance addressing the use of social media platforms and the Internet.

Interested persons were originally given until September 16, 2014, to submit comments on the draft guidance.

II. Request for Comments

Following publication of the June 18, 2014, notice, FDA received a request for additional time to develop meaningful and thoughtful comments, especially in light of the concurrent comment period with another draft guidance entitled ''Internet/Social Media Platforms: Correcting Independent Third-Party Misinformation About Prescription Drugs and Medical Devices'' published elsewhere in this volume of the **Federal Register**.

FDA has considered the request and will reopen the comment period for an additional 30 days. The Agency believes that an additional 30 days allows