

mailed to consumers) × \$16.56 per hour.<sup>8]</sup>

As elaborated on above, staff estimates that a total of 14,560 labor hours will be needed to negotiate or renegotiate outsourced service contracts annually (or as conditions otherwise change) to increase internet (8,320 hours) and telephone (6,240 hours) capacity requirements for internet web services and the automated telephone call center. This will result in approximately \$953,971 per year in labor costs. [14,560 hours × \$65.52 per hour<sup>9]</sup>

Thus, estimated cumulative labor will costs are \$7,276,430.

### G. Capital/Non-Labor Costs

As in the previous PRA clearance analysis, FTC staff believes it is likely that consumer reporting agencies will use third-party contractors (instead of their own employees) to increase the capacity of their systems. Because of the way these contracts are typically established, these costs will likely be incurred on a continuing basis, and will be calculated based on the number of requests handled by the systems. Staff estimates that the total annual amount to be paid for services delivered under these contracts is \$11,931,500.<sup>10</sup>

### H. Net Burden for FTC, After 50:50 Split

After halving the updated estimates to split the PRA burden with the CFPB regarding the Rule, the FTC's burden totals are 198,176 hours, \$3,638,215 in associated labor costs, and \$5,965,750 in non-labor/capital costs.

## III. Request for Comment

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before October 5, 2015. Write "Subpart N of Regulation V, PRA Comment, P125403" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including to the extent practicable, on the public Commission Web site, at <http://www.ftc.gov/os/publiccomments.shtm>. As a matter of discretion, the Commission tries to remove individuals' home contact information from

comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which is . . . privileged or confidential" as provided in section 6(f) of the FTC Act 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c).<sup>11</sup> Your comment will be kept confidential only if the FTC General Counsel grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <https://ftcpublishcommentworks.com/ftc/regulationVsubpartNpra>, by following the instructions on the web-based form. If this Notice appears at <http://www.regulations.gov/#/home>, you also may file a comment through that Web site.

If you file your comment on paper, write "Subpart N of Regulation V, PRA Comment, P125403" on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street, SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024. If possible, submit your paper comment to

the Commission by courier or overnight service.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before October 5, 2015. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see <http://www.ftc.gov/ftc/privacy.htm>.

David C. Shonka,

Principal Deputy General Counsel.

[FR Doc. 2015-19378 Filed 8-5-15; 8:45 am]

BILLING CODE 6750-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2004-D-0500] (formerly Docket No. 2004D-0042)

### Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs; Revised Draft Guidance for Industry (Revision 2); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the reissuance of a revised draft guidance for industry (Revision 2) entitled "Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs." We are reissuing the revised draft guidance to incorporate animal prescription drugs. This reissued revised draft guidance, when finalized, will assist manufacturers, packers, and distributors (firms) of human prescription drugs, including biologics, and animal prescription drugs, with meeting the brief summary requirement for prescription drug advertising and the requirement that adequate directions for use be included with promotional labeling for prescription drugs when print materials are directed toward consumers.

**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 reissued revised draft guidance before it

<sup>8</sup> See *Occupational Employment and Wages—May 2014*, Table 1, available at <http://www.bls.gov/news.release/ocwage.nr0.htm> (Office and administrative support workers, general).

<sup>9</sup> See *supra* notes 4 and 5.

<sup>10</sup> This consists of an estimated \$7,913,500 for automated telephone cost (\$1.33 per request × 5.95 million requests) and an estimated \$4,018,000 (\$0.14 per request × 28.7 million requests) for Internet web service cost. Per unit cost estimates are based on staff's knowledge of the industry.

<sup>11</sup> In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c), 16 CFR 4.9(c).

begins work on the final version of the guidance, submit either electronic or written comments on the reissued revised draft guidance by October 5, 2015. Submit either electronic or written comments on the proposed collection of information by October 5, 2015.

**ADDRESSES:** Submit written requests for single copies of the reissued revised draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave. Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002; or to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the revised draft guidance document.

Submit electronic comments on the reissued revised draft guidance 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:* Julie Chronis, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20993-0002, 301-796-1200.

*Regarding human prescription 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:* Thomas Moskal, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. Rockville, MD 20855-2792, 240-402-6251.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the reissuance of a revised draft guidance for industry entitled "Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs." We are

reissuing the revised draft guidance to incorporate animal prescription drugs; there are no other revisions to the revised draft guidance for industry issued February 9, 2015 (80 FR 6998).

As stated previously, the revised draft guidance updates prior FDA policy and describes the Agency's current thinking regarding the brief summary requirement for consumer-directed print prescription drug advertisements. Specifically, the revised draft guidance includes recommendations for developing a consumer brief summary and notes that, so long as firms include appropriate information in a print advertisement as outlined in the revised draft guidance, FDA does not intend to object for a failure to include certain other information.

Additionally, the revised draft guidance provides new recommendations regarding the adequate directions for use requirement for consumer-directed print promotional labeling for prescription drug products. Although the requirement in 21 CFR 201.100(d) and 21 CFR 201.105(d) for firms to provide adequate information for use is generally fulfilled by providing the full FDA-approved package insert (PI), the revised draft guidance provides that, in exercising its enforcement discretion, FDA does not intend to object for failure to include the full PI with consumer-directed print promotional labeling pieces if firms include the appropriate information as outlined in the revised draft guidance, *i.e.*, the same information in the consumer brief summary. This recommendation is designed to standardize the information consumers receive in print prescription drug product advertisements and promotional labeling and to make information more understandable to consumers.

FDA issued a draft guidance in the **Federal Register** of February 10, 2004 (69 FR 6308), entitled "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements." FDA requested comments on whether the draft guidance provided sufficient guidance on the content of the consumer brief summary and also requested research results on potential formats for the consumer brief summary. Comments, suggestions, and research were submitted to Docket No. 2004D-0042 and were carefully analyzed and considered before developing the revised draft guidance.

FDA issued the revised draft guidance in the **Federal Register** of February 9, 2015, giving interested parties an opportunity to submit comments by

May 11, 2015. We are reissuing the revised draft guidance to incorporate animal prescription drugs; there are no other revisions to the revised draft guidance issued February 2015.

The revised draft guidance incorporates information from recent social science research, clarifies the risk information that should be included in the consumer brief summary, and recommends several formatting options for this information. The revised draft guidance also recommends the use of consumer-friendly language and visual techniques to improve accessibility for consumers. Additionally, the revised draft guidance recommends that firms not disseminate the full PI to fulfill the requirements in § 201.100(d) for consumer-directed print promotional labeling for prescription drugs. Rather, the revised draft guidance recommends that firms provide the same content and format created for the consumer brief summary. FDA is issuing the revised guidance as a draft to allow for public comment on the recommendations.

The reissued revised draft guidance is being issued consistent with FDA's good guidance practices regulations (21 CFR 10.115). The reissued revised draft guidance, when finalized, will represent FDA's current thinking on the brief summary and adequate directions for use requirements. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**II. The Paperwork Reduction Act of 1995**

Under the Paperwork Reduction Act of 1995 (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 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. The revised draft guidance also refers to previously approved collection of information found in FDA regulations.

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 collected; and (4) ways to minimize the burden of information collected on the respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

**Title:** Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs.

**Description of Respondents:** Respondents to this collection of information are manufacturers, packers, and distributors (firms) of human and animal prescription drug products, including biological products for use in humans.

**Burden Estimate:** The reissued revised draft guidance pertains to the brief summary requirement for prescription drug advertising and the requirement that adequate directions for use be included with promotional labeling for human and animal prescription drugs

when print materials are directed toward consumers.

The reissued revised draft guidance, in part, explains FDA's current policy position that FDA does not intend to object for failure to include the entire PI to fulfill the requirements of §§ 201.100(d) and 201.105(d)(1) for promotional labeling pieces directed toward consumers, if firms instead provide information on the most serious and the most common risks associated with the product, while omitting less important information. Specifically, FDA recommends that any Boxed Warning, all Contraindications, certain information regarding Warnings and Precautions (*i.e.*, the most clinically significant information from the Warnings and Precautions section of the PI, information that would affect a decision to prescribe or take a drug, monitoring or laboratory tests that may be needed, special precautions not set forth in other parts of the PI, and measures that can be taken to prevent or mitigate harm), and the most frequently occurring Adverse Reactions should be included.

Furthermore, FDA recommends that information should include the indication for the use being promoted. Information regarding patient directives (such as "discuss with your health care provider any pre-existing conditions" or "tell your health care provider if you are taking any medications") should also be included. Other types of information

may be included if relevant to the drug or specific indication referred to in the promotional material(s). A statement should be included that more comprehensive information can be obtained from various sources, including the firm.

Thus, the reissued revised draft guidance recommends that firms disclose certain information to others in place of the PI to fulfill the requirements in §§ 201.100(d) and 201.105(d). This "third-party disclosure" constitutes a "collection of information" under the PRA.

FDA estimates that approximately 400 firms subject to § 201.100(d) disseminate 24,000 consumer-directed print promotional labeling pieces annually. FDA estimates that approximately 40 firms subject to § 201.105(d) disseminate 2,000 consumer-directed print promotional labeling pieces annually. FDA estimates that it will take firms approximately 10 hours to compile and draft the information needed to provide the information recommended in the revised draft guidance. Please note that the requirements related to print advertising pieces and the associated burden is already accounted for under the requirements under 21 CFR 202.1 and its approved information collection OMB control number 0910-0686 and, therefore, is not included in the burden estimate reported in table 1.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Adequate information for use: Disclosing risk information in consumer-directed promotional labeling	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Hours per disclosure	Total hours
Disclosures Related to Adequate Information for Use (§ 201.100(d)) .....	400	60	24,000	10	240,000
Disclosures Related to Adequate Information for Use (§ 201.105(d)) .....	40	50	2,000	10	20,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

This reissued revised draft guidance also refers to previously approved collections of information found in FDA regulations with respect to the brief summary requirement for print advertisements. These collections of information are subject to review by OMB under the PRA. The collection of information in § 202.1 has been approved under OMB control number 0910-0686.

III. Comments

In addition to general comments, FDA specifically requests comments on the following issues:

- In the revised draft guidance, FDA provides recommendations regarding the content and format of the consumer brief summary. Is this the most useful information for consumers to use in determining whether to take a medication or seek more information about a product, and if not, what information would be more useful?
- FDA is also interested in relevant research that has been conducted or alternative formats that were developed after we received comments on the 2004 draft guidance.
- In the revised draft guidance, FDA suggests that the adequate directions for use requirement be fulfilled by

providing the consumer brief summary rather than the full PI for the product. FDA seeks comments regarding this recommendation.

Persons who commented on the version of the revised draft guidance issued in February 2015 do not need to resubmit their comments. When finalizing the revised draft guidance, we will review comments received on this reissued version, as well as the version issued February 2015.

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It

is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

#### IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>, or <http://www.regulations.gov>.

Dated: July 31, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-19244 Filed 8-5-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Program Expansion for the National Center for Medical Home Implementation Cooperative Agreement at the American Academy of Pediatrics

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

**ACTION:** Notice of Single-Case Deviation from Competition Requirement for Program Expansion for the National Center for Medical Home Implementation Cooperative Agreement at the American Academy of Pediatrics, Grant Number U43MC09134.

**SUMMARY:** HRSA announces its intent to award a program expansion supplement in the amount of \$300,000 for the National Center for Medical Home Implementation (NCMHI) cooperative agreement. The purpose of the NCMHI cooperative agreement, as stated in the funding opportunity announcement, is to: (1) Support a national resource and technical assistance effort to implement and spread the medical home model to all children and youth, particularly children with special health care needs (CSHCN), children who are vulnerable and/or medically underserved, and pediatric populations served by state

public health programs, MCHB, and HRSA; and (2) support activities of the Healthy Tomorrows Partnership for Children Program (HTPCP) grantees to improve children's health through innovative community-based efforts, and community and statewide partnerships among professionals in health, education, social services, government, and business. The purpose of this notice is to award supplemental funds to develop the Rural IMPACT project to support activities related to child health in rural and underserved communities by the American Academy of Pediatrics, the cooperative agreement awardee who serves as the NCMHI, during the budget period of July 1, 2015, to June 30, 2016. The NCMHI is authorized by the Social Security Act, Title V, Sections 501(a)(1)(D) and 501(a)(2)), (42 U.S.C. 701).

The NCMHI is a national resource to implement and spread the medical home model to all children and youth, particularly children with special health care needs and children who are vulnerable and/or medically underserved. The NCMHI supports activities of the Healthy Tomorrows Partnership for Children Program grantees to improve children's health through innovative community-based efforts, and community and statewide partnerships among professionals in health, education, social services, government, and business.

#### SUPPLEMENTARY INFORMATION:

*Intended Recipient of the Award:* The American Academy of Pediatrics.

*Amount of the Non-Competitive*

*Award:* \$300,000.

*CFDA Number:* 93.110.

*Current Project Period:* July 01, 2008–June 30, 2018.

*Period of Supplemental Funding:* July 1, 2015–June 30, 2016.

*Authority:* Social Security Act, Title V, sections 501(a)(1)(D) and 501(a)(2), (42 U.S.C. 701).

*Justification:* The White House Rural Council is leading a Rural Child Poverty Initiative, the Rural IMPACT Project, to support improved well-being and upward economic mobility of children in rural and tribal communities. In collaboration with the White House Rural Council, HRSA, and the Administration for Children and Families, each using its own authority, used fiscal year (FY) 2015 funds to support a cohort of 10 rural and Tribal communities to provide two-generation, bundled services to children and families in need. Utilizing the two-generation approach, the communities will promote problem solving at the community level by encouraging

pediatric clinicians' participation and public-private partnership, such as the Early Childhood Comprehensive Systems Initiative, Project Launch, and private sector support for improved collaboration and coordination of and access to mental, oral, and physical health and non-clinical resources (e.g. home visiting, early care and education settings such as child care and Head Start, early intervention, child welfare, education) at the community level for children, youth, and their families.

In 2013, following objective review of its application, HRSA awarded to the American Academy of Pediatrics (AAP) cooperative agreement funding for the NCMHI. If approved, this would be the first project expansion supplement for this project.

Through the NCMHI, the AAP is working to link key state and community programs, such as Title V, school-based health centers, Head Start, and Early Intervention, which are critical, natural access points for building and strengthening integrated service delivery systems for women, children, and their families. Working with the Healthy Tomorrows Partnership for Children Program grantees and the AAP Council on Community Pediatrics Rural Health Special Interest Group, the NCMHI supports activities that promote access to quality, patient/family-centered and culturally effective services for children, youth and their families, particularly in rural and underserved communities.

The proposed Rural IMPACT Project activities align with the current project plan, as the NCMHI advances system changes and new initiatives at the community, state, and national levels, building on community partnerships to support family-centered medical home implementation for all children and youth, particularly those underrepresented and from diverse communities (Goal 3). The AAP, working with MCHB, would establish an expert workgroup and operational structure to guide the initiative; develop and issue a solicitation and scoring process and conduct a review of applications to make recommendations for participating communities; develop a quality improvement package; identify systems-level measures to monitor process and progress of individual communities and the initiative as a whole, and provide structured technical assistance to the selected communities.

#### FOR FURTHER INFORMATION CONTACT:

Marie Y. Mann, MD, MPH, FAAP, Division of Services for Children with Special Health Needs, Maternal and Child Health Bureau, Health Resources