DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 20

[Docket No. FDA–2012–N–0205]

Agreements and Memoranda of Understanding Between the Food and Drug Administration and Other Departments, Agencies, and Organizations

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: We are publishing this companion proposed rule to the direct final rule on ''Agreements and Memoranda of Understanding Between the Food and Drug Administration and Other Departments, Agencies, and Organizations,'' which makes technical changes intended to update a requirement that many of these agreements and memoranda of understanding (MOUs) be published in the **Federal Register**. Because we already post and will continue to post our ongoing agreements and MOUs with other departments, Agencies, and organizations on our Web site upon their completion, this requirement is no longer necessary. This proposed rule, accordingly, would eliminate it. We are proposing these technical changes to conserve Agency time and resources, reduce government paperwork, and eliminate unnecessary **Federal Register** printing costs while continuing to afford public access to these documents.

DATES: Submit either electronic or written comments on or before June 6, 2012. If we receive any significant adverse comments, we will publish a document withdrawing the direct final rule within 30 days after the comment period ends. We will then proceed to respond to comments under this proposed rule using the usual notice and comment procedures.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2012–N–0205 by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *FAX:* 301–827–6870.
- *Mail/Hand delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2012–N–0205 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Daniel W. Sigelman, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–4706, FAX: 301–847–8616, email: *daniel.sigelman@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 3, 1974 (39 FR 35697), we announced that copies of all our MOUs transacted with government Agencies and nongovernment organizations were available for public review at our offices during working hours and would be published in the **Federal Register**. We subsequently codified this policy in the **Federal Register** of December 24, 1974 (39 FR 44602 at 44651), and recodified it where it currently appears in § 20.108 (21 CFR 20.108) in the **Federal Register** of March 22, 1977 (42 FR 15616 at 15625).

Consumers, industry, professional groups, associations, educators, and other government Agencies had manifested widespread interest in the texts of these MOUs. The intent of § 20.108 was to promote transparency by providing access to these stakeholders.

This proposed rule would eliminate the requirement in current § 20.108(c) that our agreements and MOUs with other departments, Agencies, and organizations be published in the **Federal Register** on an individual basis and instead will require that they be posted on our Web site. We increasingly rely on Internet-based communications to ensure and promote transparency in our operations and activities. So it is with this proposed rule, which would merely recognize and codify our already established practice of making our ongoing agreements and MOUs with other departments, Agencies, and organizations publicly available on our Web site. At the time of this writing, each such publicly disclosable agreement and MOU can be accessed at one of the following three Food and Drug Administration (FDA) Web site locations:

http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/default.htm;
http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/AcademiaMOUs/default.htm; or
http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/OtherMOUs/default.htm.

Because all publicly disclosable agreements and MOUs are posted on our Web site, it is no longer necessary to require, as does current § 20.108(b), that a permanent file of them be available for public review during working hours in the Agency's Freedom of Information Public Room. Accordingly, the proposed rule would revise current § 20.108(b).

The public's access to an FDA Web site that is regularly updated to include agreements and MOUs as they are completed has already greatly enhanced the speed, ease, and convenience with which stakeholders can obtain and review these documents.

Our proposed technical changes would lessen demands on the time of our staff and reduce the Government paperwork and printing costs associated with **Federal Register** publication of newly completed agreements and MOUs with other departments, Agencies, and organizations. At the same time, it would continue to ensure, consistent with the underlying intent of § 20.108, the accessibility of records of widespread interest to consumers, industry, professional groups, associations, educators, and other government Agencies.

Currently, § 20.108(c) treats our cooperative work-sharing agreements with State or local government Agencies differently from our agreements and MOUs with other Agencies and organizations. Because these cooperative work-sharing agreements rarely vary significantly from one another, we decided against publishing their full texts in the **Federal Register**

(51 FR 19851, June 3, 1986). Instead, since 1993, we have merely required them to be listed at least once every 2 years in the **Federal Register** (58 FR 48794, September 20, 1993). This proposed rule would end such disparate treatment. Proposed § 20.108(b) would apply to all of our written agreements and MOUs with other departments, Agencies, and organizations, including cooperative work-sharing agreements with State or local government Agencies, except for signed agreements and MOUs relating to activities of our Office of Criminal Investigations, which are addressed in § 20.108(d), which would be revised and redesignated as § 20.108(c).

This proposed rule would not amend § 20.108(a) (stating that our written agreements and MOUs are available for public disclosure).

II. Companion Document to Direct Final Rulemaking

This proposed rule is a companion to the direct final rule published elsewhere in this issue of the **Federal Register**. The direct final rule and this companion proposed rule are substantively identical. This companion proposed rule provides the procedural framework within which the rule may be finalized in the event that any significant adverse comment is received in response to the direct final rule and it is withdrawn. FDA is publishing the direct final rule because we believe the rule is noncontroversial, and we do not anticipate receiving any significant adverse comments. If no significant adverse comment is received in response to the direct final rule, no further action will be taken related to this proposed rule. Instead we will publish a document confirming the effective date within 30 days after the comment period ends, confirming when the direct final rule will go into effect.

If we receive any significant adverse comment regarding the direct final rule, we will withdraw the direct final rule within 30 days after the comment period ends and proceed to respond to all of the comments under this companion proposed rule using usual notice-and-comment rulemaking procedures under the Administrative Procedures Act (APA) (5 U.S.C. 552a *et seq.*). The comment period for this companion proposed rule runs concurrently with the comment period for the direct final rule. Any comments received under this companion proposed rule will also be considered as comments regarding the direct final rule, and vice versa. We will not provide additional opportunity for comment. A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether an adverse comment is significant and warrants withdrawing a direct final rule, we will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process in accordance with section 553 of the APA (5 U.S.C. 553). Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered adverse under this procedure. For example, a comment recommending an additional change to the rule will not be considered a significant comment unless the comment states why the rule would be ineffective without the additional change. In addition, if a significant adverse comment applies to part of a rule and that part can be severed from the remainder of the rule, we may adopt as final those parts of the rule that are not the subject of a significant adverse comment.

In the **Federal Register** of November 21, 1997 (62 FR 62466), we announced the availability of the guidance document entitled ''Guidance for FDA and Industry: Direct Final Rule Procedures.'' This guidance document may be accessed at *http://www.fda.gov/RegulatoryInformation/Guidances/ucm125166.htm.*

III. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule would not impose any significant costs, we propose to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. We do not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Paperwork Reduction Act of 1995

We have concluded that this proposed rule contains no ''collections of information. '' Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

V. Environmental Impact

We have determined under 21 CFR 25.33 that this proposed rule is of a type that would not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we tentatively conclude that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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 and they may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 20 be amended as follows:

PART 20—PUBLIC INFORMATION

1. The authority citation for 21 CFR part 20 continues to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

2. Amend section 20.108 as follows:

a. Revise paragraph (b);

b. Remove paragraph (c);

c. Redesignate paragraph (d) as paragraph (c);

d. Revise newly redesignated paragraph (c).

The revisions and redesignations read as follows:

§ 20.108 Agreements between the Food and Drug Administration and other departments, Agencies, and organizations.

* * * * *

(b) All written agreements and memoranda of understanding between FDA and any entity, including, but not limited to other departments, Agencies, and organizations will be made available through the Food and Drug Administration Web site at *http://www.fda.gov* once finalized.

(c) Agreements and understandings signed by officials of the Food and Drug Administration with respect to activities of the Office of Criminal Investigations are exempt from the requirements set forth in paragraph (b) of this section. Although such agreements and understandings will not be made available through the Food and Drug Administration Web site, these agreements will be available for disclosure in response to a request from the public after deletion of information that would disclose confidential investigative techniques or procedures, or information that would disclose guidelines for law enforcement investigations if such disclosure could reasonably be expected to risk circumvention of the law.

Dated: March 16, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–6969 Filed 3–22–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 202

[Docket No. FDA–2009–N–0582]

RIN 0910–AG27

Direct-to-Consumer Prescription Drug Advertisements; Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period on specific data.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period on specific data related to a proposed rule published in the **Federal Register** of March 29,, to establish standards that would be considered in determining whether the major statement in direct-to-consumer (DTC) television and radio advertisements relating to the side effects and contraindications of an advertised prescription drug intended for use by humans is presented in a clear, conspicuous, and neutral manner. In the **Federal Register** of January 27, 2012, FDA announced that it had added a document to the docket for the proposed rulemaking concerning a study entitled ''Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in Direct-to-Consumer Prescription Drug Television Advertisements'' (Distraction Study) and the public was given until February 27, 2012, to comment on this study as it relates to the proposed standards. FDA is reopening the comment period for the rulemaking proceeding in response to a request for more time to submit comments to the Agency.

DATES: Submit either electronic or written comments on the Distraction Study report as it relates to the proposed standards by April 9, 2012.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2009–N–0582 and/or Regulatory Information Number (RIN) 0910–AG27, by any of the following methods.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *FAX:* 301–827–6870.
- *Mail/Hand delivery/Courier (For paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name, docket number, and RIN for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

For information concerning human drug products: Ernest S. Voyard, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3276, Silver Spring, MD 20993–0002, 301–796–3832.

For information concerning human biological drug products: Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 29, 2010 (75 FR 15376), FDA published a proposed rule entitled ''Direct-to-Consumer Prescription Drug Advertisements; Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner,'' to amend its regulations concerning DTC advertisements of prescription drugs. Specifically, the proposed rule would implement a new requirement of the