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By direction of the Commission.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

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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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations concerning direct-to-consumer (DTC) advertisements of prescription drugs. Specifically, the proposed rule would implement a new requirement of the Federal Food, Drug, and Cosmetic Act (the act), added by the Food and Drug Administration Amendments Act of 2007 (FDAAA), that the major statement in DTC television or radio advertisements (or ads) relating to the side effects and contraindications of an advertised prescription drug intended for use by humans be presented in a clear, conspicuous, and neutral manner. FDA is also proposing, as directed by FDAAA, standards that the agency would consider in

determining whether the major statement in these advertisements is presented in the manner required by FDAAA.

DATES: Submit written or electronic comments on the proposed rule by June 28, 2010. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by April 28, 2010, (see section "VI. Paperwork Reduction Act of 1995" of this document). See section II.D of this document for the proposed effective date of a final rule based on this proposed rule.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2009-N-0582 and/or RIN 0910-AG27, by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the "Paperwork Reduction Act of 1995" section of this document).

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, disk, 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 Regulatory Information Number (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(s), 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.

The information collection provisions of this proposed rule have been submitted to OMB for review. Interested persons are requested to fax comments

regarding information collection by April 28, 2010, to the Office of Information and Regulatory Affairs, OMB. To ensure that comments on 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 e-mailed to oir_submission@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT:

For information concerning human drug products: Marissa Chaet Brykman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 3238, Silver Spring, MD, 20993-0002, 301-796-1200; or *For information concerning human biological 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

Section 502(n) of the 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 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 current prescription drug advertising regulations in § 202.1 (21 CFR 202.1) describe requirements for print and broadcast advertisements. 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 side effects and contraindications of the advertised product in either the audio or audio and visual parts of the presentation (§ 202.1(e)(1)); this disclosure is known as the "major statement" (Ref. 1).¹

¹ If a broadcast advertisement omits the major statement, or if the major statement minimizes the major side effects and contraindications associated with the use of the drug, the advertisement could render the drug misbranded in violation of the act, 21 U.S.C. 352(n) and section 201(n) of the act (21

The current regulations further specify that an advertisement does not satisfy the 502(n) statutory requirement of containing a “true statement” of certain information if it: (1) Is false or misleading with respect to side effects, contraindications, or effectiveness; or (2) fails to present a fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug; or (3) fails to reveal material facts in light of the representations made in the advertisement or with respect to the consequences that may result from the use of the drug as recommended or suggested in the advertisement (§ 202.1(e)(5)). The regulations describe circumstances where advertisements may be false, lacking in fair balance, or otherwise misleading, including when an advertisement “fails to present information relating to side effects and contraindications with a prominence and readability reasonably comparable with the presentation of information relating to effectiveness of the drug, taking into account all implementing factors such as typography, layout, contrast, headlines, paragraphing, white space, and any other techniques apt to achieve emphasis” (§ 202.1(e)(7)(viii)).

Thus, under the current regulations the presentation of risk information in an advertisement for a prescription human or animal drug is required to be comparable in prominence and readability to the presentation of effectiveness information in the advertisement. If an advertisement presents effectiveness information in a clear and conspicuous manner, risk information is required to be presented in a comparable manner.

A. New FDAAA Requirements for DTC Radio and Television Ads

Section 901(d)(3)(A) of FDAAA (Public Law No. 110–85) amended the act by adding to section 502(n) the provision that “[i]n the case of an advertisement for a drug subject to section 503(b)(1) presented directly to consumers in television or radio format and stating the name of the drug and its conditions of use, the major statement relating to side effects and contraindications shall be presented in a *clear, conspicuous, and neutral manner*” (emphasis added). This amendment augments FDA’s existing authority by requiring television and radio advertisements for human prescription drugs to present the major statement (i.e., the disclosure of the

major side effects and contraindications of the drug) in a clear, conspicuous, and neutral manner, regardless of the manner in which effectiveness information is presented in the advertisement. In this document, section 502(n) of the act, as amended by section 901(d)(3)(A) of FDAAA, will be referred to as “section 502(n) as amended.”

Section 901(d)(3)(B) of FDAAA states that “[n]ot later than 30 months after the date of the enactment of the Food and Drug Administration Amendments Act of 2007, the Secretary of Health and Human Services shall by regulation establish standards for determining whether a major statement relating to side effects and contraindications of a drug, described in section 502(n) of the Federal Food, Drug, and Cosmetic Act * * * is presented in the manner required under such section.” As instructed by this provision of FDAAA, we are proposing standards for determining whether a major statement is presented in a “clear, conspicuous, and neutral manner” in DTC television and radio advertisements for prescription drugs intended for use by humans.²

B. Standards of Other Federal Agencies for Clear and Conspicuous

In developing the proposed standards set forth in this rule, FDA has considered standards developed by other Federal agencies (including the Federal Trade Commission (FTC), the Department of Treasury (DOT), the Commodity Futures Trading Commission (CFTC), and the Securities Exchange Commission (SEC)) for determining whether disclosures in television and radio advertisements, as well as disclosures in other contexts, are “clear and conspicuous.” These standards are described in this document. Many of these standards are highly relevant to the current rulemaking in that they also aim to ensure that required disclosures are effectively presented so that consumers are not misled or deceived about the attributes of the product or service that is the subject of the communication. The purpose of the standards proposed here is similar: The effective communication of risk information in major statements in consumer-directed

² Note that section 502(n) as amended applies only to “television or radio” broadcast advertisements, whereas FDA’s regulations at § 202.1(e)(1) apply to advertisements broadcast through “radio, television, or telephone communications systems.” Consistent with section 502(n) as amended, the proposed requirements in this rule are limited to television and radio advertisements.

prescription drug ads so that consumers receive a fair and accurate impression of the drug being promoted.

FTC regulates the advertising of a variety of products, including over-the-counter (OTC) drugs, dietary supplements, and certain medical devices.³ To prevent unfair or deceptive acts or practices, it has issued statements and regulations that establish standards for determining whether disclosures in both broadcast and print advertisements are clear and conspicuous. For example, in 1970, FTC issued an enforcement policy statement (Ref. 2) that set forth the following standards for determining whether an affirmative disclosure in a television commercial is “clear and conspicuous”:

1. The disclosure should be presented simultaneously in both the audio and video portions of the television commercial (dual modality);

2. The video portion of the disclosure must contain letters of sufficient size so that it can easily be seen and read on all television sets, regardless of picture tube size;

3. The video portion of the disclosure should contain letters of a color or shade that readily contrast with the background, and the background should consist of only one color or shade;

4. No other sounds, including music, should occur during the audio portion of the disclosure;

5. The video portion of the disclosure should appear on the screen for a sufficient duration to enable it to be completely read by the viewer (“presentation rate”); and

6. The audio and video portions of the disclosure should immediately follow the specific sales presentations to which they relate and should occur each time the representation is presented during the advertisement.

The enforcement policy further states that “[t]elevision advertisers should also consider the audience to whom the disclosure is directed in order to assure that persons (such as children) can understand the full meaning of the disclosure”.

Similarly, in the **Federal Register** of May 6, 1998 (63 FR 24996 at 25002), FTC summarized the factors it takes into account in determining whether audio messages, such as radio ads, are “clear and conspicuous” as follows:

1. Volume;
2. Cadence;
3. Placement of a disclosure; and

³ FTC has jurisdiction over OTC drug advertising under 15 U.S.C. 52, and its authority over device advertising extends to devices that are not restricted devices. See section 502(q) and (r) of the act.

4. The existence of any sounds that detract from the effectiveness of the disclosure.

FTC has also provided specific requirements for “clear and conspicuous” disclosures under the Telephone Disclosure and Dispute Resolution Act of 1992 (Public Law 102–556) (Telephone Disclosure Act). This legislation, in part, mandated that certain required disclosures appear in the advertising of pay-per-call services and directed FTC to prescribe regulations to govern the advertising of these services to avoid the abuse of consumers. In the **Federal Register** of August 9, 1993 (58 FR 42364), FTC issued regulations under the Telephone Disclosure Act that mandate that these required disclosures in advertising of pay-per-call services “be made ‘clearly and conspicuously’” (16 CFR 308.3(b)(2), (c)(2), (d)(2), and (f)(2)). The regulations at 16 CFR 308.3(a) set forth the following standards for these disclosures:

1. The disclosures shall be made in the same language as that principally used in the advertisement.
2. Television video and print disclosures shall be of a color or shade that readily contrasts with the background of the advertisement.
3. In print advertisements, disclosures shall be parallel with the base of the advertisement.
4. Audio disclosures, whether in television or radio, shall be delivered in a slow and deliberate manner and in a reasonably understandable volume.
5. Nothing contrary to, inconsistent with, or in mitigation of, the required disclosures shall be used in any advertisement in any medium; nor shall any audio, video, or print technique be used that is likely to detract significantly from the communication of the disclosures.
6. In any program-length commercial, required disclosures shall be made at least three times (unless more frequent disclosure is otherwise required) near the beginning, middle, and end of the commercial.

FTC has also issued guides for environmental marketing claims. These guides state that to be effective, the required qualifications or disclosures “should be sufficiently clear, prominent and understandable to prevent deception. Clarity of language, relative type size and proximity to the claim being qualified, and an absence of contrary claims that could undercut effectiveness, will maximize the likelihood that the qualifications and disclosures are appropriately clear and prominent” (16 CFR 260.6(a)). Similar standards for “clear and conspicuous”

were set forth by Congress in House Report 102–839, which was written to accompany the House bill (H.R. 3865), the National Waste Reduction, Recycling, and Management Act (NWRMA). This bill directed the Administrator of the Environmental Protection Agency (EPA), in consultation with FTC, to set, among other things, standards and criteria for common environmental marketing claims being used in advertising to inform consumers about the environmental impact or environmental attributes of a package or product during any part of its life cycle (Ref. 3). House Report 102–839 states that “[a] disclosure in a broadcast commercial [for environmental marketing claims] is considered *clear and conspicuous* if, in the case of an oral broadcast, it is as clear and understandable in pace and volume as other information, and, in the case of a visual broadcast, it is presented against a contrasting background and is displayed for sufficient duration and in large enough letters to be read easily” (emphasis added).

In addition to these standards for disclosures in advertisements, a number of Federal regulations provide similar standards in contexts other than advertising for disclosures that are required to be presented in a “clear and conspicuous” manner to consumers. For example, in 2000 and 2001, a number of Federal agencies, including FTC, SEC, DOT, and CFTC, provided standards for “clear and conspicuous” disclosures in regulations that were implemented as a result of the privacy provisions of the Gramm-Leach-Bliley Act (Public Law 106–102) (GLB Act). Subtitle A of title V of the GLB Act, captioned “Disclosure of Nonpublic Personal Information,” stated, among other things, that a financial institution must provide its customers with “notice” of its privacy policies and practices. These notices, which can be written or electronic, are required by regulations issued by the above agencies to be “clear and conspicuous” such that “[the] notice is reasonably understandable and designed to call attention to the nature and significance of the information in the notice.” See 16 CFR 313.3(b)(1); 12 CFR 40.3(b)(1), 216.3(b)(1), 332.3(b)(1), 573.3(b)(1); and 17 CFR 160.3(b)(1), 248.3(c)(1). The regulations give examples of when notices meet these standards. Specifically, a notice is clear or “reasonably understandable” if it:

1. Presents the information in the notice in clear, concise sentences, paragraphs and sections;
2. Uses short explanatory sentences or bullet lists whenever possible;

3. Uses definite, concrete, everyday words and active voice whenever possible;

4. Avoids multiple negatives;

5. Avoids legal and highly technical business terminology whenever possible; and

6. Avoids explanations that are imprecise and readily subject to different interpretations.

See 16 CFR 313.3(b)(2)(i); 12 CFR 40.3(b)(2)(i), 216.3(b)(2)(i), 332.3(b)(2)(i), 573.3(b)(2)(i); and 17 CFR 160.3(b)(2)(i), 248.3(c)(2)(i). A notice is conspicuous or “designed to call attention” if it:

1. Uses a plain-language heading to call attention to the notice;
2. Uses a typeface and type size that are easy to read;
3. Provides wide margins and ample line spacing;
4. Uses boldface or italics for key words; and
5. Uses distinctive type size, style, and graphic devices, such as shading or sidebars when the notice is combined with other information.

See 16 CFR 313.3(b)(2)(ii); 12 CFR 40.3(b)(2)(ii), 216.3(b)(2)(ii), 332.3(b)(2)(ii), 573.3(b)(2)(ii); and 17 CFR 160.3(b)(2)(ii), 248.3(c)(2)(ii).

Overall, FDA believes that the standards described previously for “clear and conspicuous” disclosures provide appropriate information for the agency to use in developing its own standards for evaluating major statements. Several of the policies and regulations described previously are similar to the ones set forth in this proposed rule in that they apply to consumer comprehension of disclosure information in television and radio advertisements. Furthermore, in issuing these standards, the previously mentioned agencies and Congress had goals similar to those of FDA in this rulemaking—ensuring that required information is effectively communicated to consumers so that consumers are not misled or deceived. For these reasons, we believe it is appropriate to propose standards in this rule consistent with those used by the previously mentioned agencies.

We further note that common themes are seen throughout these other standards for “clear and conspicuous” disclosures. These themes include ease of comprehension of the language used in the disclosure; the formatting and location of textual information in the disclosure; audio considerations such as pacing, volume, and qualities of speech; and the presence of any distracting elements during the disclosure. We believe that these factors all contribute to whether the audience will notice, attend to, and comprehend the risk

information presented in the major statement in television and radio ads. Therefore, we believe it is appropriate to incorporate these themes into our standards for determining whether the major statement in a television or radio advertisement for a prescription drug is presented in a clear and conspicuous manner.

C. Standards for Neutral

FDA is not aware of any previous standards or regulations concerning the definition of “neutral manner” in the context of required disclosures. FDA considers “neutral manner” to mean “unbiased manner” and has proposed standards accordingly. (See section II of this document.) In addition, FDA conducted a study on the impact of distraction on consumer understanding of risk and benefit information in DTC prescription drug television broadcast advertisements (72 FR 47051, August 22, 2007). FDA recognizes the tradeoff in this study between the specificity and control of the research setting, and consequently the utility of the findings (and their generalizability) to the field as a whole. FDA also intends to carry out further empirical studies on how best to provide consumers risk and benefit information in DTC advertisements (see, for example, 74 FR 29490, June 22, 2009). However, despite these limitations, FDA believes that the results of this study may provide helpful information for the agency to consider in determining whether a major statement is presented in a “neutral” manner. FDA is in the process of analyzing the results of the study and plans to place a report of the results of its analyses in the docket once they are complete. We will provide an opportunity for public comment on the results of the analyses either during the existing comment period or through reopening the comment period if necessary.

II. Proposed Amendments

Section 502(n) as amended requires that in DTC television or radio advertisements for prescription drugs intended for use by humans, the major statement relating to the side effects and contraindications of an advertised prescription drug be presented in a clear, conspicuous, and neutral manner. FDA proposes to implement the new FDAAA requirements for DTC television and radio advertisements by revising and adding to current § 202.1(e)(1) of the agency’s prescription drug advertising regulations.

A. Major Statement in DTC Television and Radio Advertisements

The second sentence of current § 202.1(e)(1) includes specific requirements for advertisements broadcast through media such as radio, television, or telephone communications systems. The agency is proposing to make this current provision a separate paragraph, proposed § 202.1(e)(1)(i), with the heading “Broadcast advertisements.” The agency is also proposing to add to the provision the term “major statement” in parentheses after the phrase “major side effects and contraindications” to reflect the terminology used in section 502(n) as amended.⁴

B. Proposed Standards for Clear, Conspicuous, and Neutral

FDAAA also directed FDA to establish standards for determining whether a major statement is presented in a “clear, conspicuous, and neutral manner” in DTC television and radio advertisements for prescription drugs intended for use by humans. FDA is proposing these standards in proposed § 202.1(e)(1)(ii) with the heading “Clear, conspicuous, and neutral manner.” As presented in proposed § 202.1(e)(1)(ii), a major statement would be considered to be presented in this manner if:

1. Information is presented in language that is readily understandable by consumers;
2. Audio information is understandable in terms of the volume, articulation, and pacing used;
3. Textual information is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily; and
4. The advertisement does not include distracting representations (including statements, text, images, or sounds or any combination thereof) that detract from the communication of the major statement.

These standards are consistent with the factors described and discussed in FDA’s draft guidance for industry entitled “Presenting Risk Information in Prescription Drug and Medical Device Promotion” (Ref. 4).

Standard # 1: The language used to communicate risks in the major statement must be comprehensible to the intended audience of the ad. Thus,

⁴ FDA is interpreting the term “major statement” in the statutory requirement that was added to section 502(n) of the act to refer to the disclosure of information relating to the “major” side effects and contraindications of the advertised drug that is required in broadcast advertisements under existing § 202.1(e)(1).

while promotional materials directed to health care professionals can reasonably describe risks in medical language, promotional materials directed to consumers should use everyday words or terms that are understandable to consumers. For example, if a drug’s approved prescribing information includes a risk of “syncope,” a consumer-directed ad should mention a risk of “fainting,” rather than using the medical term “syncope.” The major statement should also avoid the use of vague terms or explanations that are readily subject to different interpretations. For example, if a drug’s prescribing information indicates that more than half of patients taking the drug experienced a particular adverse event, the major statement should accurately convey the frequency of this risk (e.g., “more than half”) rather than vaguely indicating that “some patients experienced” the particular adverse event.

Standard # 2: Audio-related factors such as volume, articulation, and pacing can add to or detract from consumer comprehension of the major statement. For example, markedly reducing volume or delivering the major statement in an inarticulate manner hinders the audience’s comprehension of the risks being presented. Pacing is another critical speech consideration. Risk information must be presented at a pace that allows the audience to hear and process it. If it is presented in a manner that is too quick for the audience to process or is otherwise inarticulate, it would not be considered to be clear and conspicuous.

Standard # 3: When information from the major statement is conveyed in the visual as well as the audio portion of a television ad, this information must be placed in a manner that allows it to be easily read, such as parallel with the base of the ad. This information must also be placed such that it appears concurrently with any directly related audio information. There must also be sufficient contrast between visually-presented text and the background to highlight the risk information. If a television ad presents risk information in a way that would make it difficult to discern (e.g., using white letters on a light gray background or gray letters on a black background), the presentation would lack appropriate conspicuousness. The contrast between text displayed on the screen and the background color of the screen influences the prominence of the text once attention has been gained, and must be designed so that the risk information can be easily seen and read. Furthermore, the text must remain on

the screen for sufficient time to allow for consumers to identify and read and process the information. Font size and type style are additional factors that FDA will consider when evaluating whether the major statement is communicated in the required manner (Refs. 5 through 10). For example, the presentation of a small visual superscript in a television ad is not likely to be effective in communicating information. Visual risk presentations must be in a type size and style that allows them to be easily read by viewers.

Standard # 4: When elements of the advertisement such as images, text, graphics or sounds are presented in such a way as to significantly detract from the major statement, consumers are likely to be deterred from attending to and comprehending the risk information being presented. To achieve a “neutral,” unbiased presentation of the major statement and to avoid undercutting its effectiveness, the major statement must not be presented in competition with other elements if these elements would arrest the attention and distract consumers from the presentation of the risk information. Examples of these elements may include, but are not limited to, visuals, images, graphics or background music, sound effects, or other noises. This is of particular concern when the distracting elements convey additional benefit information, with the result being that risk information is not effectively communicated and a biased picture (i.e., one that is heavily weighted towards benefit information) of the product is conveyed by the ad.

FDA believes that consideration of these standards will result in major statements in consumer ads that effectively communicate the risk information needed for consumers to receive a fair and accurate impression of the prescription drug product being promoted. FDA recognizes that these standards require judgment in their application. Therefore, the agency does not intend to prescribe a set formula for “clear, conspicuous, and neutral” major statements because there is more than one way to achieve these standards in a television or radio ad. FDA intends to be flexible enough to consider the variety of techniques sponsors may use to appropriately convey required risk information in prescription drug ads. Sponsors have the flexibility to be creative in designing their ads as long as all of the standards listed here are complied with such that the major statement is communicated effectively to consumers and the overall message that the advertisement—including the

major statement—conveys to consumers is accurate and non-misleading.

FDA will continue to evaluate these standards to ensure that they result in consumer-directed ads that effectively communicate necessary risk information in a clear, conspicuous, and neutral way. We specifically request any comments on standards to establish “neutral.” In addition, FDA considered adding a fifth standard that would require that the major statement in television advertisements be included in both the audio and visual parts of the presentation (see also section V.H of this document). This approach is similar to the FTC standard, which states that for disclosures in a television advertisement to be clear and conspicuous, they should be presented simultaneously in both the audio and video (Ref. 2). We believe presenting the major statement in both the audio and visual portions of television ads could enhance the clarity, conspicuousness, and neutrality of this information. While this proposed rule does not contain such a standard, we are soliciting public comment on whether the final rule should contain a standard requiring that major statements in television ads be presented in both the audio and visual parts of the ad.

C. Minor Changes

We are also proposing minor changes to update § 202.1(e)(1) and make the regulation clearer. We are proposing to add punctuation, including setting off with commas the phrase “unless adequate provision is made for dissemination of the approved or permitted package labeling in connection with the broadcast presentation,” and to replace the word “shall” with the word “must” in the two places it is found in § 202.1(e)(1).

D. Proposed Effective Date

In accordance with FDAAA, the requirement that the major statement in DTC television and radio advertisements be presented in a clear, conspicuous and neutral manner has been in effect since March 25, 2008. FDA proposes that the standards in any final rule that may issue based on this proposal become effective 90 days after its publication in the **Federal Register**. Any DTC television or radio ad for a prescription drug intended for use by humans that airs on or after the effective date will be required to comply with the standards. FDA seeks public comment on its proposed 90 day effective date for any final rule that may issue based on this proposed rule.

III. Legal Authority

This rule, if finalized, would amend § 202.1 in a manner consistent with the agency’s current understanding and application of this provision. FDA was directed by FDAAA to establish standards for determining whether the major statement in television and radio advertisements for prescription drugs intended for use by humans is presented in a clear, conspicuous, and neutral manner. Furthermore, FDA has the authority to take the actions proposed in this rule under various statutory provisions. These provisions include sections 201, 301, 502, 505, 512, and 701 of the act (21 U.S.C. 321, 331, 352, 355, 360b, and 371).

IV. Environmental Impact

FDA has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs 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). OMB has determined that this proposed rule is a significant regulatory action.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because small entities rarely engage in television or radio advertising of prescription drugs and the proposed changes would impose little additional cost per advertisement, the agency proposes 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 \$133 million, using the most current (2008) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

Under section 901(d)(3)(A) of FDAAA, Congress has mandated that the major statement in prescription drug television and radio advertisements be presented in a "clear, conspicuous and neutral manner." Section 901(d)(3)(B) of FDAAA mandates that FDA issue regulations that establish standards for determining whether a major statement is presented in such a manner. In accord with this legislation, the proposed rule would implement provisions of FDAAA by requiring that the major statement be presented in a clear, conspicuous, and neutral manner; and by presenting standards for determining whether such major statements are presented in a clear, conspicuous, and neutral manner.

A. Scale of Advertisements

Industry expenditures on DTC advertisements of prescription drugs have increased dramatically since 1997. Prior to 1997, the majority of DTC promotion occurred in print; companies were unclear at that time about how they could comply with the requirements applicable to broadcast media (in particular, the requirement in § 202.1(e)(1) that advertisers make "adequate provision" for dissemination of the product's package labeling). In 1997, FDA issued a draft guidance describing an approach for fulfilling the requirement for adequate provision in connection with broadcast advertising for prescription products (Ref. 1). Following the issuance of the draft guidance, companies expanded their

consumer-directed promotional efforts to include broadcast advertisements. Advertising expenditures increased as companies began to use the costlier medium of broadcast to promote their products to consumers. From a reported total expenditure of less than \$1 billion in 1997 (Ref. 11), industry spending on DTC advertisements for prescription drugs peaked at \$4.9 billion in 2007, before declining to \$4.4 billion in 2008 (Ref. 12). This amount far exceeded the \$387 million spent on professional journal advertising, but was somewhat less than the \$6.5 billion spent on detailing efforts by industry sales representatives in that year (Ref. 12), and only a fraction of the \$14.1 billion retail value of free samples distributed in 2008 (Ref. 13). In contrast, the total value of U.S. prescription drug sales reached almost \$300 billion in 2008 (Ref. 14).

In 2008, FDA's Center for Drug Evaluation and Research (CDER) reviewed 271 DTC television advertisements and 94 radio advertisements for products under their jurisdiction. The television ads were submitted by 41 companies and the radio ads were submitted by 20 companies. The Center for Biologics Evaluation and Research (CBER) reviewed 10 DTC television ads from 2 companies and 5 radio ads from 3 companies. Overall, 48 different companies submitted advertisements to 1 or more centers in 2008.

B. Need for Regulation

Section 502(n) as amended requires that the major statement be presented in a clear, conspicuous, and neutral manner, but the statute and our current regulations do not describe standards for what FDA would consider clear, conspicuous, and neutral. This proposed rule is needed to implement this statutory requirement.

Further, in discussing the need for Federal regulatory action, OMB has

advised Government agencies that "[w]hen it is time-consuming or costly for consumers to evaluate complex information about products or services (e.g., medical therapies), they may expect government to ensure that minimum quality standards are met" (Ref. 15). OMB continues, however, that "the mere possibility of poor information processing is not enough to justify regulation. If you think there is a problem of information processing that needs to be addressed, it should be carefully documented." Therefore, the following discussion: (1) Addresses the percentage of recent television and radio advertisements that do not include clear, conspicuous, and neutral presentations of risk information, (2) describes the effects of unclear presentations on consumer understanding of product risks, and (3) explores the health consequences that may result from these misunderstandings.

C. Baseline Practice

To develop a baseline estimate of the percentage of major statements that were not presented in a clear, conspicuous, and neutral manner, FDA's Division of Drug Marketing, Advertising, and Communications (DDMAC) in CDER examined a randomly selected sample of 35 television and radio drug advertisements disseminated in 2008. As shown in table 1 of this document, this survey found that approximately one-third of the reviewed advertisements could be judged in violation of a clear, conspicuous, and neutral standard. Such results clearly suggest that current regulatory and statutory requirements have not adequately prevented the broadcast of a significant number of potentially misleading or deceptive discussions of product risk.

TABLE 1.—DDMAC'S REVIEW OF RADIO AND TELEVISION ADVERTISEMENTS FROM 2008

Outcome	Radio ads (n=5)	Television ads (n=30)	Overall (n=35)
Violates existing fair balance regulations and violates clear, conspicuous, and neutral (CCN) statute	2	7	9
Violates only existing fair balance regulations	1	1	2
Does not violate existing fair balance regulations but violates CCN statute	0	3	3
Does not violate existing fair balance regulations and does not violate CCN statute	2	19	21
Does not violate CCN statute	3 (60%)	20 (67%)	23 (66%)
Violates CCN statute	2 (40%)	10 (33%)	12 (34%)

We understand, however, that this survey may not be indicative of present and future television and radio promotions. First, television advertisements have a relatively short life and typically run for about 3 months to a year (Ref. 16). The affected firms will have had several years since the 2007 enactment of FDAAA to refine later broadcast advertisements. Moreover, the Pharmaceutical Research and Manufacturers of America's (PhRMA's) publication of voluntary guidelines regarding DTC advertisements was revised in December 2008, to (among other things) specify that risks and safety information in DTC advertising should be presented in a "clear, conspicuous and neutral manner, and without distraction from the content" (Ref. 17). This guideline may influence industry performance and thereby decrease the number of television and radio advertisements that fail to present risk information in a clear, conspicuous, and neutral manner. Therefore, we expect that industry compliance would improve significantly over the sample in table 1 of this document by the time a final rule takes effect. Those DTC television and radio advertisements that do not comply with the new standards at the time a final rule takes effect would, however, need to be revised or removed. To refine this baseline for analysis, FDA seeks public comment and industry data on pertinent trends in pharmaceutical television and radio promotions.

D. Effects on Consumer Understanding

The preceding discussion demonstrates that a significant number of recent broadcast advertisements have failed to present a clear, conspicuous, and neutral discussion of prescription drug risks. These omissions may be at least partially responsible for a lack of consumer comprehension of product hazards. When risk messages are presented in a vague or difficult to understand manner, they are easily misinterpreted and consumers are more likely to be misled. For example, 60 percent of the responding physicians in one large survey believed that DTC advertisements for prescription drugs provided patients with little or no understanding about the risks and negative effects of the products (Ref. 18). Over 65 percent of these physicians observed that DTC advertisements may lead patients to confuse the relative risks and benefits of advertised drugs. The proposed rule would help address this lack of understanding by providing standards for the major statement in television or radio advertisements for prescription drugs.

E. Health Consequences

To the extent that risk information in current DTC advertisements is not presented in a clear, conspicuous, and neutral manner, this proposed rule could potentially have a positive effect on health outcomes through better communication of the risk information in prescription drug television and radio advertisements. The magnitude of these potential health benefits would vary with the influence of these promotions on consumer health decisions.

The growing body of research on the influence of DTC advertisements on public health has generated mixed results. The agency contracted with Eastern Research Group (ERG) in 2008 to review and summarize the relevant peer-reviewed literature on DTC advertising published between 2004 and 2008 (Ref. 19). This review was an extension of work already published by FDA in 2004 summarizing its survey research results on the public health impacts of DTC advertising (Ref. 18). Highlights of some of the research findings in the ERG report are described as follows. See the ERG report for a comprehensive discussion of the literature covered by the review.

The purpose of DTC prescription drug advertising is to increase the demand for the advertised prescription drugs, and researchers have generally found that to have happened. In addition, some research has shown that DTC advertising for a particular drug increased the demand for the entire therapeutic class. Other effects include increased rates of drug therapy compliance, although the size of this effect may be small. DTC advertising has also been shown to produce indirect, or spillover, effects on consumer behavior, such as increasing the number of physician visits that detect treatable disease (Ref. 20).

On the other hand, positive outcomes are less probable when drug promotions are biased and provide an incomplete or confusing account of the drug's likely effects. Some analysts find that DTC ads cause physicians to waste valuable time responding to patient requests (Ref. 21) and can encourage an increased and sometimes inappropriate demand for the advertised products (Ref. 21 and 22).

This proposed rule could potentially improve the communication of risk information, thereby resulting in the audience receiving a more accurate net impression of the product's benefits and risks. We cannot quantify the magnitude of the health impact resulting from a potential improvement in risk communication because of the absence of studies that analytically assess the

full range of advantages and disadvantages of DTC advertising for prescription drugs. One survey of the literature, for example, explains that "no studies have examined the impact of direct to consumer advertising on either health outcomes or examined the costs and health and social consequences of DTCA [DTC advertising]" (Ref. 23). Likewise, FDA has identified no authoritative research on the overall health consequences of DTC advertising. Without a measure of the overall impact of DTC ads, we cannot reasonably develop a quantifiable estimate of the incremental consequences of requiring more understandable risk discussions in DTC advertising. Nevertheless, it is plausible that providing standards for presenting risk information in DTC drug advertisements in a clear, conspicuous, and neutral manner could generate positive health benefits.

F. Costs of Compliance

FDA regulations currently require that broadcast advertisements present information relating to the major side effects and contraindications of the product, and the 2007 FDAAA requires that such information be presented in a clear, conspicuous, and neutral manner. The proposed regulation would provide standards for what would be considered clear, conspicuous, and neutral to further consumer comprehension. Once the rule is in effect, manufacturers would have to take these standards into account when developing advertising materials for television or radio.

This proposed rule would lead to the one-time cost to advertisers of setting up new guidelines or standard operating procedures for meeting the clear, conspicuous, and neutral criteria. FDA estimates that from one-third (17) to all of approximately 50 firms who submitted advertisements would bear these one-time costs. We tentatively estimate that these revisions would require 10 to 20 hours of upper management time at \$134 per hour, 40 to 80 hours of marketing management time at a cost of \$88 per hour, and 80 to 120 hours of technical writing time at a cost of \$42 per hour.⁵ The cost per revision would range from \$8,220 to \$14,760. We estimate the total one-time costs of the revisions to range from \$140,000 (17 x \$8,220) to \$740,000 (50 x \$14,760). FDA requests comments on

⁵ Bureau of Labor Statistics, "Occupational Employment Statistics: May 2008 National Industry-Specific Occupational Employment and Wage Estimates, NAISC 325400—Pharmaceutical and Medical Manufacturing," Wages were increased by 40 percent to include fringe benefits. Downloaded January 2009. http://www.bls.gov/oes/2008/may/naics4_325400.htm

this estimated range of costs and its components.

FDA assumes that this proposed rule will not increase the length of broadcast time for radio and television ads. The requirement to present risk information in a clear, conspicuous, and neutral manner is already in effect in accordance with section 502(n) as amended. The proposed standards for determining clear, conspicuous, and neutral will provide guidance that should reduce regulatory uncertainty in developing major statements. Advertising agencies take great pains to create promotional programs that portray product attributes in the most favorable way. For the most part, advertising messages are crafted to be as persuasive as possible, while complying with applicable regulatory restrictions. In the design stage, ad developers consider and evaluate a variety of facts, features, layouts, and formats before making a final decision. The proposed rule would not require ads to be more intricate or exhaustive; on the contrary, the standards would encourage ads that are simpler and less dramatically charged. Thus, although the standards for clear, conspicuous, and neutral might constrain some design choices, the creation of compliant broadcasts would not require the use of a greater quantity of productive resources.

For the most part, key advertising agencies would be aware of the pertinent rules and would tailor their compositions accordingly. While in the short term, some additional draft submissions might occur as industry became familiar with the new standards, this incremental effort would be minimal. Indeed, because the requirement to present risk information in a clear, conspicuous, and neutral manner is already in effect in accordance with section 502(n) as amended, the issuance of defined standards should reduce regulatory uncertainty, which in turn could reduce regulatory costs.

To account for any additional burdens associated with third party disclosure attributable to section 901(d)(3)(A) and (d)(3)(B) of FDAAA, the agency estimates an additional 5 hours per television or radio advertisement would be required for about 420 ads per year, or a total burden of 2,100 hours per year (see table 2 of this document). The total cost for this burden is \$184,800 per year assuming a wage rate of \$88 per hour. Although most of this cost is associated with section 901(d)(3)(A) of FDAAA, a small fraction of this cost would be attributed to this proposed rule (section 901(d)(3)(B) of FDAAA).

Because the time period between issuance of any final rule based on this proposed rule and effective date of the final rule should be longer than the life cycle of most DTC television and radio advertisements, future advertisements should cost about the same to produce once the firm's guidelines (standard operating procedures) for clear, conspicuous, and neutral risk statements are incorporated. If the time period is not sufficient to encompass the life cycle of an advertisement, the likely response would be for the firm to revise the advertisement. Industry sources indicate that these revisions would on average cost \$100,000 to \$150,000 per television advertisement and \$10,000 to \$20,000 per radio advertisement. The agency seeks comments on this assessment of costs of compliance.

In summary, the incremental costs of compliance with this proposed rule include the following:

- a one-time cost to establish new guidelines or standard operating procedures of from \$140,000 to \$740,000;
- annual costs amounting to a small fraction of the total third party disclosure burden of \$184,800; and
- a one-time cost of from \$100,000 to \$150,000 per television advertisement and from \$10,000 to \$20,000 per radio advertisement to revise any advertisement with a life cycle extending beyond the compliance date of the final rule.

G. Distributional Effects

It is also possible that some individual firms would lose market share if forced to make their risk information more understandable. Should the provision of more understandable risk information lead to reduced demand for particular products, the proposed rule could lead to lost revenue and reduced producer surplus for individual firms. The reduced demand for particular products, however, may lead to increased demand for substitute products. Losses for firms whose products experience reduced demand could be offset by gains accruing to firms whose products experience increased demand. The effect of such changes in demand could be a net benefit to society, depending on the magnitude of any positive health outcomes associated with changes in the consumption of prescription drugs, if any. To the extent that some lost revenues are not transferred to substitute drug products, these losses would not be offset.

H. Alternatives Considered

As directed by FDAAA, the agency is proposing standards for determining whether the major statement in television and radio prescription drug advertisements is presented in a clear, conspicuous, and neutral manner. FDA considered the following alternatives to this proposed rule.

We considered, as an alternative, relying on guidance rather than regulation for providing the standards for determining clear, conspicuous, and neutral. See, for example, FDA's draft guidance for industry entitled "Presenting Risk Information in Prescription Drug and Medical Device Promotion" (Ref. 4). Guidance documents, however, are not legally enforceable. Even if most firms would comply voluntarily, FDA needs to ensure that standards would be implemented for all important risk messages in prescription drug television and radio ads. In addition, because section 901(d)(3)(B) of FDAAA requires that FDA establish standards by regulation, this alternative would not conform to the statute.

We also considered requiring specific standards for how audio and visual disclosures should be formatted in advertisements, such as specific font sizes, contrast colors, placement of textual information, and language. We concluded, however, that this level of detail was unnecessary because there is more than one way to present risk information in a clear, conspicuous, and neutral manner.

We also considered requiring that the major statement in television advertisements be included in both the audio and visual parts of the presentation. This approach is similar to the FTC standard, which states that for disclosures in a television advertisement to be clear and conspicuous, they should be presented simultaneously in both the audio and video (Ref. 2). Research has shown that presenting the same information in both the audio portion and as visual superimposed text increases the comprehension of that information compared with information presented in only one of those modes. This has been called dual-mode processing and has been shown in multiple studies on advertising to improve recall of the communicated information over and above that seen in audio mode alone (Refs. 24 and 25). In addition to these specific studies on the use of superimposed text in ads, the literature suggests that a dual mode presentation of information results in greater recall and comprehension of information in a

wide variety of situations (Refs. 26 through 30). The theories to support this finding stem from theories of basic memory processing (Ref. 31). To learn and use knowledge, information first must be encoded in memory by being attended to or noticed, then stored in memory, and then retrieved from memory. When people attend to information in two modes (visual and audio), they may form two separate codes for that same information, resulting in greater elaboration of, or thinking about, the information than they might have with only one code (Ref. 32). It is also possible that presenting the information in two modes reduces possible interference from other messages that might be present on the screen at the time of the ad. Thus, presenting the major statement in both the audio and visual portions of television ads could enhance the clarity, conspicuousness, and neutrality of this information. FDA is specifically requesting comments on this alternative.

To estimate the costs of this alternative, we assume that none of the affected firms would be compliant. Therefore, based on 2008 submissions, approximately 50 firms would incur one-time costs to modify their standard operating procedures. We calculated the range of one-time costs for the proposed rule as \$140,000 to \$740,000. Because all 50 firms would bear these costs, the one-time costs for this alternative would be in the upper end of the range, from \$410,000 to \$740,000.

In addition, existing television ads, or television ads in the final stages of production, may need to be modified to include superimposed text and other adjustments. The agency estimates that modifications of existing advertisements to comply with this alternative may cost approximately \$100,000 to \$150,000 per television advertisement. We cannot predict the number, if any, of existing advertisements that would be revised. If all of the 281 television ads from 2008 required these changes, however, the additional one-time costs would be \$28.1 to \$42.2 million. The agency requests detailed data on these cost estimates.

I. Small Business Impact

FDA finds that the proposed regulation would not have a significant impact on a substantial number of small entities. The Small Business Administration (SBA) defines as small any pharmaceutical preparations manufacturing entity (NAICS 325412) with fewer than 750 employees and any biologics product manufacturing entity (NAICS 325414) with fewer than 500

employees. Among the 48 companies submitting television or radio advertisements to FDA in 2008, only about 5 would meet the SBA definition of small entity. Thus, we estimate that only a few of the manufacturers affected by the proposed rule would be a small business. We estimate the one-time cost to revise procedures for meeting the clear, conspicuous, and neutral criteria would range from \$8,228 to \$14,760 per firm. Because the time period between issuance of any final rule based on this proposed rule and the effective date of the final rule should be longer than the life cycle of most DTC television and radio advertisements, future advertisements should cost about the same to produce once the guidelines for clear, conspicuous, and neutral risk statements are incorporated. If the time period is not sufficient to encompass the life cycle of an advertisement, the likely response would be for the firm to revise the advertisement. Using the cost of revising television advertisements as an upper bound, industry sources indicate that these revisions would on average cost \$100,000 to \$150,000 per advertisement.

Because there is wide variation in the revenues of small firms, the agency cannot assess the impact of the one-time compliance costs as a percent of average firm revenues for those small businesses that produce television ads. However, firms spend on average about \$1 million to produce a single television ad. The one-time compliance costs for adjusting procedures represents about 1 percent of the cost of a single ad. If a company needed to revise its existing advertising, the upper bound of compliance costs would range from 11 percent to 16 percent of the production cost of a single advertisement, which would be a small fraction of the firm's revenues.

Advertising agencies would not experience significant adverse economic impacts because the cost of producing compliant work products should be no greater than the cost of producing less informative advertisements. The agency seeks comments on this assessment.

VI. Paperwork Reduction Act of 1995

This proposed rule contains collections of information that are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 3520) (the PRA). "Collection of information" includes any request or requirement that persons obtain, maintain, retain, or report information to the agency, or disclose information to a third party or to the public (44 U.S.C. 3502(3) and 5 CFR 1320.3(c)). The title, description, and respondent description of the information collection are shown

under this section with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

We invite comments on these topics: (1) Whether the collection of information is necessary for 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.

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

Description: Under § 202.1, FDA establishes requirements for advertisements for human and animal prescription drug products and biological products. The regulations apply to advertisements published in journals, magazines, other periodicals, and newspapers, and advertisements broadcast through media such as radio, television, and telephone communication systems. Under § 202.1(e)(1), FDA's regulations describe when a true statement of information in brief summary relating to side effects, contraindications, and effectiveness is required. In this proposed rule, the agency is proposing to amend these regulations. Specifically, under proposed § 202.1(e)(1)(ii), FDA would implement section 502(n) as amended, which requires that the major statement in a DTC television or radio advertisement for a prescription drug intended for human use be presented in a clear, conspicuous, and neutral manner. The rule also includes proposed standards for determining whether the major statement is presented in a clear, conspicuous, and neutral manner. Television and radio advertisements subject to the requirements at proposed § 202.1(e)(1)(ii) are subject to the PRA because these advertisements disclose information to the public.

According to FDA data, CDER estimates that approximately 300 television advertisements for prescription drugs would be prepared

by approximately 30 companies under proposed § 202.1(e)(1)(ii) annually and CBER estimates that approximately 15 of these advertisements would be prepared by approximately 5 companies annually. FDA anticipates that this estimate will moderately increase in the near future. The estimated total number of television advertisements under proposed § 202.1(e)(1)(ii) would be 315. Based on its experience reviewing television advertisements, FDA estimates that approximately 5 hours on average would be needed per advertisement to comply with the

proposed requirement that the major statement in DTC television advertisements be presented in a clear, conspicuous, and neutral manner (proposed § 202.1(e)(1)(ii)).

Further, according to FDA data, CDER estimates that approximately 100 radio advertisements for prescription drugs would be prepared by approximately 20 companies under proposed § 202.1(e)(1)(ii) annually and CBER estimates that approximately 5 of these advertisements would be prepared by approximately 3 companies annually. FDA anticipates that this estimate will

moderately increase in the near future. The estimated total number of radio advertisements under proposed § 202.1(e)(1)(ii) would be 105. Based on its experience reviewing radio advertisements, FDA estimates that approximately 5 hours on average would be needed per advertisement to comply with the proposed requirement that the major statement in DTC radio advertisements be presented in a clear, conspicuous, and neutral manner (proposed § 202.1(e)(1)(ii)).

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

TABLE 2.—ESTIMATED ANNUAL THIRD PARTY DISCLOSURE BURDEN¹

21 CFR Section	Type of Submission	No. of Respondents	Annual Frequency per Disclosure	Total Annual Disclosures	Hours per Disclosure ³	Total Hours
202.1(e)(1)(ii)2	Television Advertisements	35	9	315	5	1,575
	Radio Advertisements	23	5	105	5	525
Total		58	14	420	5	2,100

¹ FDA assumes that this proposed rule will not increase the length of broadcast time for radio and television ads.

² In accordance with section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)), and 5 CFR 1320.12(b), FDA has published in the FEDERAL REGISTER a 60-day notice soliciting public comment on the collections of information that result from current § 202.1, including the estimated burden of current requirements for third party disclosures in television and radio advertisements. See 75 FR 12756, March 17, 2010.

³ The estimated hours represent the burden of complying with sections 901(d)(3)(A) and (d)(3)(B) of FDAAA as implemented by this proposed rule.

We specifically request comment on the burden hour estimates described previously in this document and in table 2 of this document.

Costs

In addition to the burden hours in table 2 of this document, FDA estimates the following costs associated with the information collection. Although the proposed rule neither requires nor recommends the creation of guidelines or standard operating procedures for meeting the clear, conspicuous, and neutral requirement, if implemented, it may lead some companies to incur a one-time cost for revising guidelines or standard operating procedures for ensuring compliance with the underlying requirement (see also section V.F of this document). We estimate that from 17 to 50 companies would bear these one-time costs, and that these revisions would require 10 to 20 hours of upper management time at \$134 per hour, 40 to 80 hours of marketing management time at a cost of \$88 per hour, and 80 to 120 hours of technical writing time at a cost of \$42 per hour. The cost per revision would range from \$8,220 to \$14,760. We estimate the total one-time costs of the revisions to range from \$140,000 (17 x \$8,220) to \$740,000 (50 x \$14,760).

Finally, although future advertisements should cost about the

same to produce once the companies' guidelines (standard operating procedures) for clear, conspicuous, and neutral risk statements are adopted, if the time period is not sufficient to encompass the life cycle of an advertisement, the likely response would be for the company to revise the advertisement. Based on industry sources, we estimate that these revisions would on average cost \$100,000 to \$150,000 per television advertisement and \$10,000 to \$20,000 per radio advertisement (see also section V.F of this document).

Description of Respondents: Manufacturers, packers, and distributors, and applicants with approved new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics licensing applications (BLAs) and those that market prescription drugs for human use without an approved application.

The information collection provisions of this proposed rule have been submitted to OMB for review. Interested persons are requested to fax comments regarding information collection by (see DATES section of this document), to the Office of Information and Regulatory Affairs, OMB. 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 e-mailed to oir_submission@omb.eop.gov. All comments should reference the title of this rule and include the FDA docket number found in brackets in the heading of this document.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule does not contain policies that 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, the agency has concluded 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.

VIII. Request for Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that

individuals may submit one paper copy. Comments are to be identified 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.

IX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

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3. H. Rept. No. 102-839, August 11, 1992.
4. FDA draft guidance for industry, "Presenting Risk Information in Prescription Drug and Medical Device Promotion," available at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM155480.pdf> (May 2009).
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12. IMS Health, *Total U.S. Promotional Spend By Type, 2008*, available at http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top_Line_Data/U.S._Promo_Spend_Data_2008.pdf, downloaded September 2009.

13. IMS Health, Integrated Promotional Services™, Year 2008, Data Extracted on September 2009.

14. IMS Health, "IMS Health Reports U.S. Prescription Sales Grew 1.3 Percent in 2008 to \$291 Billion," (www.imshealth.com, News Releases, March 19, 2009).

15. Office of Management and Budget, Circular A-4, September 17, 2003.

16. General Accounting Office, "Prescription Drugs: FDA Oversight of Direct-to-Consumer Advertising Has Limitations," GAO-03-177, p. 23, October 2002.

17. PhRMA, "PhRMA Guiding Principles: Direct to Consumer Advertisements About Prescription Medicines," revised December 2008.

18. Aikin, K., J. Swasy, and A. Braman, "Patient and Physician Attitudes and Behaviors Associated With DTC Promotion of Prescription Drugs—Summary of FDA Survey Research Results, Final Report," November 19, 2004.

19. Eastern Research Group, Inc., "Scientific Literature on Direct-to-Consumer Advertising of Prescription Pharmaceuticals, 2004-2008: Literature Review," January 2009.

20. Weissman, J.S., D. Blumenthal, A.J. Silk, et al., "Consumers' Reports on the Health Effects of Direct-to-Consumer Drug Advertising," *Health Affairs*, W3-82-W3-95, posted February 26, 2003, <http://content.healthaffairs.org/cgi/content/abstract/hlthaff.w3.82v1>.

21. Murray, E., B. Lo, L. Pollack, et al., "Direct-to-Consumer Advertising: Physicians' Views of Its Effects on Quality of Care and the Doctor-Patient Relationship," *Journal of the American Board of Family Practice*, 16(6):513-524, 2003.

22. Mintzes, B., M. Barer, R.L. Kravitz, et al., "Influence of Direct to Consumer Pharmaceutical Advertising and Patients' Requests on Prescribing Decisions: Two Site Cross Sectional Survey," *British Medical Journal*, 324:278-279, 2002.

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Communication Research, 22(1):86-115, 1995.

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List of Subjects in 21 CFR Part 202

Advertising, Prescription drugs. 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 202 be amended as follows:

PART 202—PRESCRIPTION DRUG ADVERTISING

1. The authority citation for 21 CFR part 202 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 352, 355, 360b, 371.

2. Section 202.1 is amended by revising paragraph (e)(1) to read as follows:

§ 202.1 Prescription-drug advertisements.

- * * * * *
- (e) True statement of information in brief summary relating to side effects, contraindications, and effectiveness:
- (1) *When required.* All advertisements for any prescription drug ("prescription drug" as used in this section means drugs defined in section 503(b)(1) of the act and § 201.105, applicable to drugs for use by man and veterinary drugs, respectively), except advertisements described in paragraph (e)(2) of this section, must present a true statement of information in brief summary relating to side effects, contraindications (when used in this section "side effects, contraindications" include side effects, warnings, precautions, and contraindications and include any such information under such headings as cautions, special considerations, important notes, etc.), and effectiveness.
- (i) *Broadcast advertisements.* Advertisements broadcast through media such as radio, television, or telephone communications systems must include information relating to the major side effects and contraindications ("major statement") of the advertised drugs in the audio or audio and visual parts of the presentation and, unless adequate provision is made for dissemination of the approved or permitted package labeling in

connection with the broadcast presentation, must contain a brief summary of all necessary information related to side effects and contraindications.

(ii) *Clear, conspicuous, and neutral manner.* Advertisements for prescription drugs intended for use by humans presented directly to consumers in television or radio format must present the major statement in a clear, conspicuous, and neutral manner. A major statement is clear, conspicuous, and neutral if:

(A) Information is presented in language that is readily understandable by consumers;

(B) Audio information is understandable in terms of the volume, articulation, and pacing used;

(C) Textual information is placed appropriately and is presented against a contrasting background for sufficient duration and in a size and style of font that allows the information to be read easily; and

(D) The advertisement does not include distracting representations (including statements, text, images, or sounds or any combination thereof) that detract from the communication of the major statement.

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Dated: March 24, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-6996 Filed 3-26-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 514, and 558

[Docket No. FDA-2010-N-0155]

Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA or the agency) is announcing an advance notice of proposed rulemaking (ANPRM) to solicit comments from the public regarding potential changes to its current regulation relating to veterinary feed directive (VFD) drugs. FDA's VFD regulation, which became effective on January 8, 2001, established requirements relating to the distribution and use of VFD drugs and animal feeds containing such drugs. FDA is

undertaking a review of these requirements in an effort to identify possible changes to improve efficiency. Therefore, the agency is requesting public comment on all aspects of the VFD regulation, particularly suggestions relating to improving efficiency. This information may be used to help draft a proposed rule in the near future.

DATES: Submit electronic or written comments by June 28, 2010.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2010-N-0155, 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, disk, 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 number 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: Neal Bataller, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-9201, e-mail: Neal.Bataller@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Before 1996, two options existed for regulating the distribution of animal drugs, including drugs in animal feed: (1) Over-the-counter (OTC) and (2) prescription. In 1996, Congress passed and the President signed into law the Animal Drug Availability Act (ADAA) (Public Law 104-250), to facilitate the

approval and marketing of new animal drugs and medicated feeds. As part of the ADAA, Congress determined that certain new animal drugs should be approved for use in animal feed but only if these medicated feeds were administered under a veterinarian's order and professional supervision. Therefore, the ADAA created a new category of products called veterinary feed directive drugs (or VFD drugs). VFD drugs are new animal drugs intended for use in or on animal feed which are limited to use under the professional supervision of a licensed veterinarian in the course of the veterinarian's professional practice.

In the **Federal Register** of December 8, 2000 (65 FR 76924), FDA issued a final rule amending the new animal drug regulations to implement the VFD-related provisions of the ADAA. FDA reaffirmed that certain new animal drugs should be approved for use in animal feed only if these medicated feeds are administered under a veterinarian's order and professional supervision. Veterinarian oversight is important for assuring the safe and appropriate use of certain new animal drugs. For example, safety concerns relating to the difficulty of disease diagnosis, drug toxicity, drug residues, antimicrobial resistance, or other reasons may dictate that the use of a medicated feed be limited to use by order and under the supervision of a licensed veterinarian.

It has been 9 years since FDA began implementing the final rule regulating VFDs. Although, currently there are few approved VFD animal drug products, FDA has received a number of informal general comments that characterize the current VFD process as being overly burdensome. In addition, there are concerns that the process in its current form will become particularly problematic to administer in the future as the number of approved VFD animal drugs increases. When veterinary oversight of a medicated feed is determined to be necessary, it is critically important that such oversight be facilitated through an efficient VFD process. In response to these concerns, the agency is undertaking a review of the VFD regulations to determine whether changes are warranted to improve the program's efficiency.

II. Agency Request for Comments

The purpose of this document is to solicit public comment on whether such efficiency improvements are needed and, if so, on possible revisions to the VFD regulations. Such comments are welcome on all aspects of the VFD regulation. To facilitate FDA's review of