Direct-to-Consumer Prescription Drug Advertisements; Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner – Proposed Rule
SUPPORTING STATEMENT

JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is proposing to amend its regulations concerning direct-to-consumer (DTC) advertisements of prescription drugs. 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.

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."

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).

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, FDA is 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.

FDA is proposing 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 advertisements regulations. 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. FDA is proposing the 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

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.

2. Purpose and Use of the Information Collection

Section 901(d)(3)(A) of FDAAA 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." 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." FDA is proposing to implement the new requirement in section 502(n) 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. As instructed by FDAAA, FDA is also proposing standards for determining whether a major statement is presented in a "clear, conspicuous, and neutral manner."

FDA concurs with Congress that the proposed rule is needed because existing regulations do not adequately assure that consumers are not misled or deceived by the discussion of side effects and contraindications in television and radio advertisements for prescription drugs intended for use by humans. Specifically, while the regulations currently require that broadcast ads include information relating to the major side effects and contraindications (commonly referred to as the "major statement") of the advertised drug, and section 502(n) as amended requires that the major statement be presented in a clear, conspicuous, and neutral manner, the statute and regulations do not describe standards for what FDA would consider clear, conspicuous, and neutral.

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 proposed standards 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.

3. Use of Improved Information Technology and Burden Reduction

FDA has issued the following guidance documents, among others, to explain the process for submitting information to the agency in electronic format:

- "Providing Regulatory Submissions in Electronic Format-—Prescription Drug Advertising and

Promotional Labeling." This guidance discusses issues related to the electronic submission of advertising and promotional labeling materials for prescription drug and biological products.

• "Providing Regulatory Submissions in Electronic Format-—General Considerations." This guidance discusses general issues common to all types of electronic regulatory submissions.

These guidance documents and others are available at FDA's web site http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

4. Efforts to Identify Duplication and Use of Similar Information

The proposed requirement does not duplicate nor is it similar to any current requirements, except for the statutory requirement directing FDA to promulgate this rulemaking.

5. Impact on Small Businesses or Other Small Entities

Section V of the proposed rule, “Analysis of Impacts” (the analysis), stated that the proposed regulation would not have a significant impact on a substantial number of small entities. According to the analysis, 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, the analysis estimates that only a few of the manufacturers affected by the proposed rule would be a small business. The analysis estimates a one-time cost to revise procedures for meeting the clear, conspicuous, and neutral criteria that 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 adopted. 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 ads.

6. Consequences of Collecting the Information Less Frequently

As explained above, Section 901(d)(3)(A) of FDAAA 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." 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." FDA is issuing this proposed rulemaking as instructed by FDAAA. Any less frequent collection of information would be in conflict with the statutory requirements.

7. Special Circumstances Relating to the Guidelines in 5 CFR 1320.5

There are no special circumstances relating to this provision.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

This burden analysis is for a proposed rule, which will give ample opportunity for public comment. The comments will be summarized and responded to in the final rule.

9. Explanation of Any Payment or Gift to Respondents

There is no payment or gift to respondents associated with this proposed rule.

10. Assurance of Confidentiality Provided to Respondents

Confidentiality of the information submitted under these requirements is protected under 21 CFR 314.430 and under 21 CFR part 20. The unauthorized use or disclosure of trade secrets required in applications is specifically prohibited under Section 310(j) of the Act.

11. Justification for Sensitive Questions

There are no sensitive questions associated with this proposed rule.

12. Estimates of Annualized Hour Burden and Costs

Hour Burden -

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. The agency is proposing to amend these regulations in the following ways: Under proposed § 202.1(e)(1)(ii), FDA would implement section 502(n) as amended, which requires that the major statement in DTC television or radio advertisements for a prescription drug intended for use by humans 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 1.--Estimated Annual Third Party Disclosure Burden [1]

21 CFR Section	Type of Submission	Number 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] The third party disclosure burden estimates and other reporting burden estimates for current § 202.1 are the subject of a separate request for OMB approval. See 75 FR 12756, March 17, 2010.
[3] The estimated hours represent the burden of complying with sections 901(d)(3)(A) and (B) of FDAAA as implemented by the proposed rule.

Costs –

The industry burden estimate calculated above would result in labor costs. Using a wage rate of $88 per hour for loaded industry labor costs, times 2,100 hours calculated above for the information collection resulting from this new requirement, results in $184,800 in total labor costs13. Estimates of Other Total Annual Cost Burden to Respondents and Recordkeepers

Section V of the proposed rule, “Analysis of Impacts” (the analysis), examined the impacts of

the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612). The analysis concluded that the proposed rule is a significant regulatory action as defined by the Executive order. In addition, because most small entities rarely engage in television or radio advertising of prescription drugs and the proposed changes would impose little additional cost per advertisement, in the analysis the agency proposed to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

As discussed in the analysis, although the proposed rule neither requires or 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 to revise guidelines or standard operating procedures for ensuring compliance with the underlying requirement. The analysis estimated that from 17 to 50 firms 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. The analysis estimated the total one-time costs of the revisions to range from $140,000 (17 x $8,220) to $740,000 (50 x $14,760).

The analysis also explained that 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 adopted. However, 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. Based on industry sources, the analysis indicated that these revisions would on average cost $100,000 to $150,000 per television advertisement and $10,000 and $20,000 per radio advertisement.

14. Annualized Cost to the Federal Government

FDA currently devotes approximately 37 FTEs to the review of submissions required under 21 CFR 202.1. FDA does not anticipate that this number will have to be increased as a result of the proposed rule.

15. Explanation for Program Changes or Adjustments

This is a proposed rule.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans for tabulation and publication and project time scheduling.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB expiration data will be displayed where required.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no new FDA forms or publications associated with this rulemaking.

PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the supporting statement, and any additional documentation to: Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

1. Agency/Subagency originating request

FDA

2. OMB control number b. [ ] None

a. 0910 -

3. Type of information collection (*check one*)

a. [x] New Collection

b. [ ] Revision of a currently approved collection

c. [ ] Extension of a currently approved collection

d. [ ] Reinstatement, without change, of a previously approved collection for which approval has expired

e. [ ] Reinstatement, with change, of a previously approved collection for which approval has expired

f. [ ] Existing collection in use without an OMB control number

For b-f, note Item A2 of Supporting Statement instructions

4. Type of review requested (*check one*)
a. [x] Regular submission
b. [ ] Emergency - Approval requested by at close of comment period
c. [ ] Delegated

5. Small entities
Will this information collection have a significant economic impact on a substantial number of small entities? [ ] Yes [x] No

6. Requested expiration date
a. [X] Three years from approval date b. [ ] Other Specify:____/___

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

8. Agency form number(s) (*if applicable*)

9. Keywords human drugs advertising labeling

10. Abstract: The proposed rule would implement a new requirement of the Federal Food, Drug, and Cosmetic 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.

11. Affected public (*Mark primary with "P" and all others that apply with "x")*
a. ___ Individuals or households d. ___ Farms
b. _x_ Business or other for-profit e. ___ Federal Government
c. ___ Not-for-profit institutions f. ___ State, Local or Tribal Government

12. Obligation to respond (*check one*)
a. [ ] Voluntary- (guidance document)
b. [x] Required to obtain or retain benefits
c. [Mandatory

13. Annual recordkeeping and reporting burden
a. Number of respondents – 58 _____
b. Total annual disclosures – 420 _____
1. Percentage of these responses collected electronically – 25%
c. Total annual hours requested – 2,100 _____
d. Current OMB inventory – new collection___
e. Difference 0 _____
_____

14. Annual reporting and recordkeeping cost burden *(in thousands of dollars)*
a. Total annualized capital/startup costs 0_____
b. Total annual costs (O&M) 0_____
c. Total annualized cost requested _0_____
d. Current OMB inventory 0_____
e. Difference _____
f. Explanation of difference This is a proposed rule___
1. Program change _____
2. Adjustment _____

15. Purpose of information collection (*Mark primary with "P" and all others that apply with "X"*)
a. _ Application for benefits e._ Program planning or management
b. _ Program evaluation f._ Research

16. Frequency of recordkeeping or reporting *(check all that apply)*
a. [ ] Recordkeeping b. [X] Third party disclosure
c. [x] Reporting
1. [x] On occasion 2. [ ] Weekly 3. [ ] Monthly

c. _ General purpose statistics g. P Regulatory or compliance d. _ Audit	4. [ ] Quarterly 5. [ ] Semi-annually 6. [] Annually 7. [ ] Biennially 8. [ ] Other (describe) _
17. Statistical methods Does this information collection employ statistical methods [ ] Yes [x] No	18. Agency Contact (person who can best answer questions regarding the content of this submission) Name: Elizabeth Berbakos Phone: _____