Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

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; Notice of Availability of Study Data

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period on specific data related to a proposed rule published in the **Federal Register** of March 29, 2010 (75 FR 15376), to establish standards that would be considered in determining whether the major statement in direct-to-consumer (DTC) television and radio advertisements relating to the side effects and contraindications of an advertised prescription drug intended for use by humans is presented in a clear, conspicuous, and neutral manner. FDA is announcing that it has added a document to the docket for the proposed rulemaking concerning a study entitled: ''Experimental Evaluation of the Impact of Distraction on Consumer Understanding of Risk and Benefit Information in Direct-to-Consumer Prescription Drug Television Advertisements'' (Distraction Study). This study was designed to investigate some advertising factors that could influence consumers' understanding of a drug's risks. This document reopens the comment period for the rulemaking proceeding to allow an opportunity for comment on the study as it relates to the proposed standards.

DATES: Interested persons may submit either electronic or written comments on the Distraction Study report as it relates to the proposed standards by February 27, 2012.

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

Electronic Submissions

Submit electronic comments in the following way:

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

Written Submissions

Submit written submissions in the following ways:

- *FAX:* (301) 827–6870.
- *Mail/Hand delivery/Courier (For paper 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, FDA–2009–N–0582, and RIN 0910–AG27 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.

FOR FURTHER INFORMATION CONTACT:

For information concerning human drug products: Ernest S. Voyard, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Building 51, Suite 3200, Silver Spring, MD 20993–0002, (301) 796–1200.

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

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 29, 2010 (75 FR 15376), FDA published a proposed rule entitled:''Direct-to-Consumer Prescription Drug Advertisements; Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner'' to amend its regulations concerning DTC advertisements of prescription drugs. Specifically, the proposed rule would implement a new requirement of the Federal Food, Drug, and Cosmetic Act, added by section 901(d)(3)(A) of the Food and Drug Administration Amendments Act of 2007 (FDAAA). This section requires that the major statement in DTC television or radio advertisements 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, and directs FDA to publish regulations establishing the standards for determining whether a major statement meets these requirements. As directed by section 901(d)(3)(B) of FDAAA, the proposed rule described standards that the Agency would consider in determining whether the major statement is clear, conspicuous, and neutral. The proposed rule provided a 90-day period for public comment. The comment period closed June 28, 2010.

In the proposed rule (75 FR 15376 at 15379), we noted that FDA had conducted a study on the impact of distraction on consumer understanding of risk and benefit information in DTC prescription drug television advertisements (72 FR 47051, August 22, 2007) (Distraction Study). We further stated that there would be an opportunity for public comment on FDA's analyses of the results of the Distraction Study. Therefore, FDA has added the Distraction Study report to the docket and is reopening the comment period to provide an opportunity for interested parties to comment on the results of the analyses as it relates to the proposed standards.

The Distraction Study examined three factors which might influence people's understanding of the risk information in the audio portion of the advertisement: (1) The presence or absence of superimposed text, (2) the emotional (affective) tone of visual images, and (3) the consistency of the visual images

with the risk information. The results of the Distraction Study indicate that presenting risk information at the same time in text and in audio improves consumers' understanding of the risk information. The results of the Distraction Study did not find support for the idea that consumers' understanding of the risk information is influenced by the emotional (affective) tone of visual images or the consistency of the visual images with the risk information on the screen during the major statement.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding the Distraction Study as it relates to the proposed standards. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document and labeled ''ATTN: Distraction Study.'' The data and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 20, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–1672 Filed 1–26–12; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 21

[Docket No. FWS–R9–MB–2011–0033; 91200–1231–9BPP]

RIN 1018–AX82

Migratory Bird Permits; Double-Crested Cormorant Management in the United States

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Request for comments; extension of comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service, extend the comment period for public comments to guide the preparation of a Supplemental Environmental Impact Statement or Environmental Assessment on the development of revised regulations governing the management of double-crested cormorants. Under current regulations, cormorant damage management activities are conducted annually at the local level by individuals or agencies operating under USFWS depredation permits, the existing Aquaculture Depredation Order, or the existing Public Resource Depredation Order. The depredation orders are scheduled to expire on June 30, 2014. Our analysis will update the 2003 Final Environmental Impact Statement (FEIS): *Double-crested cormorant management in the United States* (USFWS 2003). If you have previously submitted comments, please do not resubmit them, because we have already incorporated them in the public record and will fully consider them in our final decision.

DATES: Electronic comments via *http://www.regulations.gov* must be submitted by 11:59 p.m. Eastern Time on April 6, 2012. Comments submitted by mail must be postmarked no later than April 6, 2012.

ADDRESSES: You may submit comments by either one of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments on Docket No. FWS–R9–MB–2011–0033.

U.S. Mail or hand delivery: Public Comments Processing, Attn: FWS–R9–MB–2011–0033; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 North Fairfax Drive, Mail Stop 2042–PDM; Arlington, VA 22203–1610.

We will not accept email or faxes. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information that you provide. See the Public Comments section below for more information.

FOR FURTHER INFORMATION CONTACT: Terry Doyle, Wildlife Biologist, at (703) 358–1799.

SUPPLEMENTARY INFORMATION:

Public Comments

We request comments and suggestions on this topic from other concerned governmental agencies, the scientific community, industry, or any other interested parties. You may submit your comments and materials concerning this issue by one of the methods listed in the **ADDRESSES** section. We will not consider comments sent by email or fax or to an address not listed in the **ADDRESSES** section.

If you submit a comment via *http://www.regulations.gov,* your entire comment—including any personal identifying information—will be posted on the Web site. If you submit a hardcopy comment that includes personal identifying information, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy comments on *http://www.regulations.gov.*

Comments and materials we receive, as well as supporting documentation we use in preparing a proposed rule, will be available for public inspection at *http://www.regulations.gov,* or by appointment, during normal business hours, at the U.S. Fish and Wildlife Service (contact the person listed under **FOR FURTHER INFORMATION CONTACT**).

Background

On November 8, 2011, we published a request for comments for consideration as we revise the regulations governing double-crested cormorant management (76 FR 69225). We requested comments on a variety of issues related to double-crested cormorants, and asked a number of questions for consideration as we develop a proposal to revise the regulations at 50 CFR 21.47 and 21.48. See that document for detailed information.

We have received requests from two Flyways for an extension of the comment period so that they may consider the regulations and management issues at their upcoming meetings. To accommodate these requests, we extend the comment period for an additional 60 days, until April 6, 2012.

Dated: January 18, 2012.

Rachel Jacobson,

Acting, Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2012–1807 Filed 1–26–12; 8:45 am]

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