proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: October 10, 2007.

Brendan C. Kelly,

Reports Clearance Officer.

[FR Doc. 07–5176 Filed 10–19–07; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0133]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Experimental Evaluation of Variations in Content and Format of the Brief Summary in Direct-to-Consumer Print Advertisements for Prescription Drugs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Experimental Evaluation of Variations in Content and Format of the Brief Summary in Direct-to-Consumer (DTC) Print Advertisements for Prescription Drugs'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4816.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 14, 2007 (72 FR 11889), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0611. The approval expires on October 31, 2010. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: October 12, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–20756 Filed 10–19–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0114]

Electronic Distribution of Prescribing Information for Prescription Drug Products; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening to December 6, 2007 the comment period for the notice that published in the **Federal Register** of April 2, 2007 (72 FR 15701); this notice was related to the public hearing of April 27, 2007, concerning the electronic distribution of FDA-approved prescribing information currently contained in the package insert (PI) for prescription drug and biological products. FDA is reopening the comment period for the sole purpose of inviting interested persons to submit comments on the concept of electronic distribution of FDA-approved prescribing information currently contained in the PI for prescription animal drug products.

DATES: Submit written or electronic comments by December 6, 2007.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Erik Mettler, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, *Erik.Mettler@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** notice of April 2, 2007 (72 FR 15701), FDA published a notice of public hearing concerning the concept of the electronic distribution of PIs for human prescription drugs and biological products and solicited relevant information and comments on this concept. The purpose was to garner views and information on the feasibility of establishing an efficient process for industry to electronically distribute prescribing information to dispensers. The PIs with prescribing information accompany prescription human drugs to meet the requirement that ''labeling on or within the package from which the drug is to be dispensed bears adequate information for its use * * *'' (21 CFR 201.100(c)(1)). For additional information, see the April 2, 2007, notice (72 FR 15701).

Currently, the PI contains the prescribing information for the safe and effective use of the product in the form of a paper leaflet. Although the information in the PI is a valuable resource, it is often not readily accessible when a healthcare provider who has not physically received the drug makes a treatment decision or discusses treatments with a patient. Additionally, the PI may not contain the most current information, because the PI accompanying the drug's distribution may have been printed and distributed prior to more recent labeling changes. Accordingly, with technological advances in the electronic transmission of information, we are considering how prescribing information could be more effectively disseminated.

FDA is reopening the comment period for the sole purpose of inviting interested persons to submit comments addressing a number of questions regarding the current use of package inserts for animal drug products and those logistical issues associated with electronic distribution of such prescribing information for animal drug products. The previous request for comments was limited to human drugs and biologics. As with prescription human drugs, the PIs with prescribing information accompany prescription animal drugs to meet the requirement that ''labeling on or within the package from which the drug is to be dispensed bears adequate information for its use * * *'' (21 CFR 201.105(c)(1)). FDA approves the prescribing information as part of both human and animal drug labeling in the drug application. The request for comment is to gain a better understanding of how PIs for animal drugs are currently used by healthcare entities as we consider new approaches for the dissemination of labeling information.

II. Issues for Discussion

FDA is specifically interested in receiving comments on the following questions and any other pertinent