FDA estimates that the burden will be insignificant because the reporting requirement reflects customary business practice. Based on discussions with an industry representative, the burden hours estimated for this collection of information is 1 hour. The operating and maintenance cost associated with this collection is $100 for preparation of labels.

Dated: March 21, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–6086 Filed 3–28–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0534]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Format and Content for Over-the-Counter Drug Product Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by April 28, 2005.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Format and Content for Over-the-Counter (OTC) Drug Product Labeling—(OMB Control Number 0910–0340)—Extension

In the **Federal Register** of March 17, 1999 (64 FR 13254), FDA amended its regulations governing requirements for human drug products to establish a standardized format for the labeling of all over-the-counter (OTC) drug products. The rule added new § 201.66 (21 CFR 201.66) and requires OTC drug product labeling to include uniform headings and subheadings, presented in a standardize order, with minimum standards for type size and other graphic features. The rule is intended to enable consumers to better read and understand OTC drug product labeling and to apply this information to the safe and effective use of OTC drug products. FDA concludes that the labeling statements required under this rule are not subject to review by the OMB because they are ''a public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and therefore do not constitute a ''collection of information'' under the PRA (44 U.S.C. 3501 *et seq.*).

Section 201.66 of the labeling requirements requires all OTC drug manufacturers to format labeling as set forth in paragraphs (c) and (d). FDA has learned from the industry that OTC drug product manufacturers routinely redesign the labeling of their products as part of their usual and customary business practice. The rule provides varied timeframes for implementing the OTC labeling requirements. Therefore, the majority of respondents have been able to format OTC drug product labeling in accordance with § 201.66 as part of their routine redesign practice, creating no additional paperwork or economic burden.

In discussing the collection of information under the PRA in the final rule (64 FR 13254 at 13274 to 13276), FDA estimated that, of the 39,310 stock keeping units (SKUs) (individual products, packages, and sizes) marketed under a final monograph when the OTC labeling requirements were issued on March 17, 1999, approximately 32 percent, or 12,573 products, may necessitate labeling format changes sooner than provided under their usual and customary practice of label design. FDA estimated that of the 400 respondents who produce OTC drug products, including the 12,573 products described above, each may be required to respond approximately 31.4 times to this rule outside of their usual and customary practice. Each response was estimated to take, on the average, 4 hours, for a total of 50,292 hours per year. This burden was expected to be a one-time burden.

FDA stated that although the usual and customary practice of label redesign would minimize the burden for the remaining 68 percent of SKUs, or 26,737 products, marketed at the time the OTC labeling requirements were issued on March 17, 1999, additional time may be necessary for each company to make the format changes under this rule. FDA estimated that of the 400 respondents who produce OTC drug products, each may be required to respond approximately 66.8 times to bring the 26,737 products into compliance with the rule. FDA estimated that for this group, each response will take an average of 2.5 hours for a total of 66,842 hours. This burden was expected to be a one-time burden.

Finally, FDA estimated that approximately 61 respondents hold new drug applications (NDAs) and abbreviated new drug applications (ANDAs) (41 NDA holders and 20 ANDA holders) for which supplements and amendments would be required. FDA expected that 522 submissions (350 to NDAs and 172 to ANDAs) would be required for labeling changes under § 201.66(c) and (d), which averages to 8.5 submissions per respondent. FDA estimated that each submission wouldtake an average of 2 hours to prepare for a total of 1,040 hours annually. This burden was also expected to be a one-time burden.

Since the final rule was issued on March 17, 1999, FDA extended the May 16, 2001, compliance date by 1 year to May 16, 2002 (with a corresponding extension of the May 16, 2002, compliance date for products with annual sales of less than $25,000 to May 16, 2003) (65 FR 38191, June 20, 2000). Since March 17, 1999, FDA has published 6 additional major final rules on OTC drug monographs and several minor amendments to existing final monographs. The effective date for relabeling the OTC drug products affected by these final monographs in the new format occurred by the end of 2004, except for OTC sunscreen drug products (for which implementation of the new labeling requirements has been stayed indefinitely while FDA amends the monograph for these products) and a small number of other OTC drug products with annual sales less than $25,000. Based on information in the 6 final rules issued since 1999, FDA estimates that 11,250 additional SKUs (out of the original 26,737 that needed to be relabeled in the new format) have

already been affected by the final rule. Thus, 15,487 SKUs remain to be affected by the OTC drug product labeling final rule, minus approximately 2,000 OTC sunscreen drug product SKUs. All of these except the sunscreen drug products will need to have the new labeling format by May 16, 2005, for products initially introduced or initially delivered for introduction into interstate commerce after that date. For these reasons, FDA considers the number of products remaining to be affected by the OTC drug products labeling final rule to be close to the number of products that were affected at the time the final rule published on March 17, 1999. FDA finds that the number of products remaining to be affected by the final rule is similar to the number of products that were estimated as initially affected in the collection of information in the final rule. Accordingly, in this notice FDA is using the same numbers of respondents, annual frequency per response, and total annual responses it estimated in 1999.

FDA believes the hours per response and total hours may be less than the numbers stated in the final rule for several reasons. First, respondents have made a number of inquiries already since the final rule was issued in 1999. FDA's experience is that inquiries have been less than 2.5 or 4 hours per response, generally averaging 0.25 to 0.5 hours per inquiry. Second, FDA has issued a guidance for industry entitled ''Labeling OTC Human Drug Products—Updating Labeling in RLDs and ANDAs'' (67 FR 64402, October 18, 2002), which included a number of labeling examples to assist holders of RLDs (reference listed drugs, i.e., the applicable innovator) and ANDAs for OTC drug products to implement the new OTC drug product labeling regulation. Third, FDA has issued two draft guidances for industry entitled ''Labeling OTC Drug Products (Small Entity Compliance Guide)'' (69 FR 71420, December 9, 2004) and ''Labeling OTC Human Drug Products—Questions and Answers'' (70 FR 2415, January 13, 2005). These guidances provide extensive additional information and examples how to implement the new OTC drug product labeling requirements.

The guidance documents should have reduced some of the hours per response and total hours for some NDA and ANDA holders and manufacturers who market products under the OTC drug monographs. However, FDA is not currently able to estimate how much the time has been reduced. Accordingly, in this notice FDA is listing the same hours per response and total hours as appeared in the final rule.

In the **Federal Register** of January 4, 2005 (70 FR 362), FDA requested comments on the proposed collections of information. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours
201.66[1]	400	31.43	12,573	4	50,292
201.66	400	66.8	26,737	2.5	66,842
201.66(c) and (d)[1]	61	8.5	522	2	1,044
201.66(e)	25	4	100	24	2,400
Total					120,578

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: March 21, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–6088 Filed 3–28–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0102]

Referral of KEMSTRO (Baclofen) and DROXIA (Hydroxyurea) for the Conduct of Pediatric Studies

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the referral of KEMSTRO (baclofen) and DROXIA (hydroxyurea) to the Foundation for the National Institutes of Health (the Foundation) for the conduct of pediatric studies. FDA referred KEMSTRO (baclofen) and DROXIA (hydroxyurea) to the Foundation on September 1, 2004, and October 20, 2004, respectively. FDA is publishing this notice of the referrals in accordance with the Best Pharmaceuticals for Children Act (BCPA).

FOR FURTHER INFORMATION CONTACT: Grace Carmouze, Center for Drug Evaluation and Research (HFD–960), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–7337.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 4 of the BPCA (Public Law 107–109), FDA is announcing the referral to the Foundation of the written requests for the conduct of pediatric studies for KEMSTRO (baclofen) and DROXIA (hydroxyurea). Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the exclusivity incentive program described in section 505A of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355a). Section 505A of the act permits certain applications to obtain 6 months of exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

The BPCA established additional mechanisms for obtaining information on the safe and effective use of drugs in pediatric patients. Specifically, section 4 of the BPCA amends section 505A(d) of the act to create a referral process to obtain studies for drugs that have patent or exclusivity protection, but for which the sponsor has declined to conduct the pediatric studies in response to a written request by FDA. Under section 4 of the BPCA, if the Secretary of Health and Human Services (the Secretary) determines that there is a continuing need for the pediatric studies described in the written request and the sponsors of the products with patent or exclusivity protection have declined to conduct the studies, the Secretary shall refer the drug to the Foundation, established under section 499 of the Public Health Service Act (42 U.S.C. 290(b)), for the conduct of the pediatric studies described in the written request (21 U.S.C. 355a(d)(4)(B)(i)). In addition, the BPCA requires public notice of the name of the drug, name of the