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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbin

[Docket No. 2006N–0104]

Agency Information Collection Activities; Proposed Collection; Comment Request; Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements contained in the requirements for submission of labeling for human prescription drugs and biologics in electronic format.

DATES: Submit written or electronic comments on the collection of information by [*insert date 60 days after date of publication in the* **Federal Register**].

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

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20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the 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.

Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format (OMB Control Number 0910–0530)—Extension

FDA is requesting that OMB extend approval under the PRA for the information collection contained in the final rule entitled "Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format" (68 FR 69009, December 11, 2003) (the final rule). The final rule amended FDA regulations governing the format in which certain labeling is required to be submitted for FDA review with new drug applications (NDAs), certain biological license applications (BLAs), abbreviated new drug applications (ANDAs), supplements, and annual reports. The final rule required that the content of labeling for prescription drug and biological products required under 21 CFR 201.100(d)(3) be submitted to FDA electronically in a form that FDA can process, review, and archive. Copies of product labeling have been required to be submitted to FDA for review in NDAs, certain BLAs, ANDAs, certain supplements, and annual reports under §§ 314.50, 314.70, 314.81, 314.94, 314.97, 314.98, 601.2, and 601.12 (21 CFR 314.50, 314.70, 314.81, 314.94, 314.97, 314.98, 601.2, and 601.12). Under these regulations, copies of labeling may be submitted electronically or on paper. The final rule added the requirement to submit the content of labeling in electronic format to simplify the drug labeling review process and speed up the approval of labeling changes.

The reporting burden for submitting labeling under §§ 314.50, 314.70, 314.81, 314.94, 314.97, and 314.98 has been estimated by FDA and the collection of information has been approved by OMB under OMB control number 0910–0001, most recently until May 31, 2008. The reporting burden

associated with current §§ 601.2 and 601.12 has also been estimated and that collection of information has been approved by OMB under OMB control number 0910–0338, most recently until September 30, 2008. We are not re-estimating these approved burdens in this action. Only the additional reoccurring reporting burdens associated with the electronic submission of the content of labeling in the final rule are estimated in this action.

New NDAs (§ 314.50), ANDAs (§ 314.94), and BLAs (§ 601.2): Based on the number of submissions during 2005 under the approved collections of information for §§ 314.50, 314.94, and 601.2, we estimate that approximately 75 NDA applicants, 160 ANDA applicants, and 6 BLA applicants (respondents) submit applications to us annually. We estimate that these applicants (respondents) submit approximately 111 NDAs, 766 ANDAs, and 21 BLAs each year that are subject to the requirements of the final rule. As explained in section V of the final rule, we estimate that the hours per response, i.e., the additional time necessary for submission of the content of labeling in electronic format for these applications, will be less than 15 minutes.

Supplements to NDAs (§ 314.70), ANDAs (§ 314.97), and BLAs (§ 601.12(f)(1) and (f)(2)): Based on the number of submissions during 2005 under the approved collections of information for §§ 314.70, 314.97, and § 601.12(f)(1) and (f)(2), we estimate that approximately 272 NDA applicants, 189 ANDA applicants, and 35 BLA applicants (respondents) submit supplements to approved applications to us annually. We estimate that these applicants (respondents) submit approximately 1,839 NDA supplements, 3,208 ANDA supplements, and 82 BLA supplements each year that are subject to the requirements of the final rule. As explained in section V of the final rule, we estimate that the hours per response, i.e., the additional time necessary

for submission of the content of labeling in electronic format for these applications, will be less than 15 minutes.

Annual Reports for NDAs (§ 314.81), ANDAs (§ 314.98), and BLAs (§ 601.12(f)(3)): Based on the number of submissions during 2005 under the approved collections of information for §§ 314.81, 314.98, and 601.12(f)(3), we estimate that approximately 306 NDA applicants, 333 ANDA applicants, and 4 BLA applicants (respondents) submit annual reports to us annually. We estimate that NDA applicants submit to us approximately 2,617 annual reports, ANDA applicants submit approximately 6,054 annual reports, and BLA applicants submit approximately 16 annual reports each year that are subject to the requirements of the final rule. As explained in section V of the final rule, we estimate that the hours per response, i.e., the additional time necessary for submission of the content of labeling in electronic format for these submissions, will be less than 15 minutes.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
New Applications					
314.50	75	1.48	111	.25	27.75
314.94	160	4.79	766	.25	191.50
601.14[2]	6	3.50	21	.25	5.25
Supplements					
314.70	272	6.76	1,839	.25	459.75
314.97	189	16.98	3,208	.25	802
601.14[3]	35	2.34	82	.25	20.5
Annual Reports					
314.81	306	8.55	2,617	.25	654.25
314.98	333	18.18	6,054	.25	1,513.50
601.14[4]	4	4	16	.25	4
Total					3,678.50

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Applications submitted under § 601.2.
[3]Supplements submitted under § 601.12(f)(1) and (f)(2).
[4]Annual reports submitted under § 601.12(f)(3).

Dated: MAR 2 0 2006

March 20, 2006.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 06–????? Filed ??–??–06; 8:45 am]

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