

draft guidance, differ because the final rule is specific to the electronic submission of labeling content for human prescription drugs and certain biologics, and the part 11 draft guidance applies to the maintenance of all electronic records and to all electronic submissions subject to part 11.

We exempted the submission of electronic labeling content from certain part 11 requirements because we believe these part 11 requirements are not critical to ensure the quality of the content of labeling submitted under this rule and we want to ensure that industry resources are not being spent on unnecessary controls. For example, validation for the system used to generate the labeling record is not necessary because the applicant's verification that the information in the labeling record is accurate serves the same objective. Our review of the content of labeling is based on the version of the labeling record submitted to us. Earlier versions of the record, as well as changes made to the earlier versions, are not relevant to our analysis. Thus, other controls related to the creation, modification, and maintenance of the labeling records are also not needed.

IV. Legal Authority

Our legal authority to amend our regulations governing the format of labeling for human prescription drugs and biologics derives from sections 201, 301, 501, 502, 503, 505, 506, 506A, 506B, 506C, 510, 513–516, 518–520, 701, 704, 721, and 801 of the act (21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 360, 360c–360f, 360h–360j, 371, 374, 379e, and 381); 15 U.S.C. 1451–1561; the Public Health Service Act (42 U.S.C. 216, 241, 262, 263, 264); and section 122, Public Law 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

V. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given below with an estimate of the annual reporting burden. Included in this estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Requirements for Submission of Labeling for Human Prescription Drugs and Biologics in Electronic Format.

Description: FDA is amending its regulations governing the format in

which certain labeling is required to be submitted for review with NDAs, certain BLAs, ANDAs, supplements, and annual reports. The final rule requires that the content of labeling for prescription drug and biological products required under § 201.100(d)(3) be submitted to FDA electronically in a form that we can process, review, and archive. Copies of product labeling are currently 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. Copies of labeling may be submitted electronically or on paper. The agency is adding the new requirements because submitting the content of labeling in electronic format will simplify the drug labeling review process and speed up the approval of labeling changes.

As required under section 3506(c)(2)(B) of the Paperwork Reduction Act, FDA provided an opportunity for public comments on May 3, 2002 (67 FR 22367), on the information collection provisions of the proposed rule. FDA received two comments stating that the agency underestimated the time and costs to prepare the content of labeling in electronic format for submission to FDA. Specifically, the comments stated that the 15 minutes to convert the labeling into PDF was underestimated because it did not take into account the time needed to proofread the content of labeling document.

FDA believes that proofreading is not an additional cost for submitting labeling in electronic format for new submissions of NDAs, BLAs, and ANDAs. Labeling is proofread prior to submission regardless of the format. If the labeling is in a word processing file, it is irrelevant whether the document is printed or converted to a PDF file. This is because the finished product, the labeling, is proofread for quality assurance in either case. We also note that someone may need even less time to proofread an electronic file than a printed document because the computer could assist in finding errors. As such, we are not changing the burden estimate for these applications in the final rule.

However, we agree that we should allow for proofreading of labeling under certain circumstances. Applicants that have previously submitted labeling in paper format in annual reports or supplements, but also maintained the labeling document in electronic format, should be provided time for proofreading the converted file. This category of labeling would not require any changes to the labeling since it was

last submitted to the agency. It only requires additional time for proofreading to ensure that the electronic document being submitted is the same as the labeling previously submitted in paper format. We estimate that the hours per response (i.e., the time it will take an applicant to submit the labeling content electronically for these annual reports and supplements) will be approximately 5 hours. We discuss this new category of reporting in more detail in this section V when we calculate the burdens associated with submission of electronic labeling in supplements and annual reports. We also add sections to the estimated annual reporting burden chart to report the burdens.

As we noted in the proposed rule, we recognize that some older annual reports may require additional steps, such as accessing the labeling in the archives, putting the content of labeling into an electronic format, and converting it to a PDF file. In response to the proofreading comments mentioned previously, we are allowing an additional 2 hours for proofreading this type of labeling (the proposed rule allowed for 8 hours and the final rule is allowing for 10 hours).

The reporting burdens for submitting labeling as currently required under §§ 314.50, 314.70, 314.81, 314.94, 314.97, and 314.98 have previously been estimated by FDA, and this collection of information was approved by OMB until March 31, 2005, under OMB control number 0910–0001. The reporting burdens associated with current §§ 601.2 and 601.12 have also previously been estimated and this collection of information was approved by OMB until August 31, 2005, under OMB control number 0910–0338 (this includes the collection of information previously approved by OMB under control number 0910–0315). We are not reestimating these approved burdens in this rulemaking. Only the additional reporting burdens associated with the electronic submission of the content of labeling are estimated.

New NDAs (§ 314.50), ANDAs (§ 314.94), and BLAs (§ 601.2): Based on data in the approved collections of information for §§ 314.50, 314.94, and § 601.2, we estimate that approximately 83 NDA applicants, 117 ANDA applicants, and 17 BLA applicants (respondents) submit applications to us annually. We estimate that these applicants (respondents) will submit approximately 85 NDAs, 323 ANDAs, and 17 BLAs each year that will be