

subject to this rule.¹⁰ Based on our experience with voluntary electronic submissions and our knowledge of the drug and biologic industries, we assume that applicants for new NDAs, ANDAs, and BLAs will already have the necessary labeling in an electronic format that can be easily accessed and converted to a PDF file. Thus, we have estimated 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. Therefore, we estimate that respondents will spend approximately 106 hours per year submitting the content of labeling to us in accordance with the final rule.

Supplements to NDAs (§ 314.70) and ANDAs (§ 314.97) and BLAs (§ 601.12(f)(1) and (f)(2)): Based on data in the approved collections of information for §§ 314.70, 314.97, and § 601.12(f)(1) and (f)(2), we estimate that approximately 418 NDA applicants, 152 ANDA applicants, and 20 BLA applicants (respondents) submit supplements to approved applications to us annually. We estimate that these applicants (respondents) will submit approximately 630 NDA supplements, 1,000 ANDA supplements, and 20 BLA supplements each year that will be subject to this rule.

Based on our experience with voluntary electronic submissions and our knowledge of the drug and biologic industries, we assume that approximately 254 NDA supplements, 396 ANDA supplements, and 10 BLA supplements will be submitted by applicants who already have the necessary labeling in an electronic format that can be easily accessed and converted to a PDF file. Thus, we have estimated that the hours per response, i.e., the additional time necessary for submission of the content of labeling in electronic format for these supplements, will be less than 15 minutes. Therefore, we estimate that respondents would spend approximately 165 hours per year submitting the content of labeling to us in these supplements under the final rule.

As mentioned previously, we are adding a new category to the paperwork section to allow for proofreading the converted file of labeling that was previously submitted in supplements in paper form (and not requiring any changes since it was last submitted), but is also maintained by the applicant in an electronic format. We estimate that approximately 376 NDA supplements,

604 ANDA supplements, and 10 BLA supplements will be submitted by applicants who previously submitted labeling in paper, but have such labeling available in electronic 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 supplements, will be approximately 5 hours. Therefore, we estimate that in the first year, respondents will spend approximately 4,950 hours submitting the content of labeling that was previously submitted in supplements in paper form. For all supplements combined, we estimate that in the first year, respondents will spend approximately 5,115 hours submitting the content of labeling to us in supplements under the final rule. This expenditure of time will only be necessary the first time that a supplement is submitted with the content of labeling in electronic format. Once the content of labeling has been converted to an electronic format, the time necessary to submit the content of labeling in subsequent supplements will be the same as that for the other types of submissions or less than 15 minutes. Therefore, we estimate that, in subsequent years, respondents will spend approximately 413 hours per year submitting the content of labeling in supplements.

Annual Reports for NDAs (§ 314.81), ANDAs (§ 314.98), and BLAs (§ 601.12(f)(3)): Based on data in the approved collections of information for §§ 314.81, 314.98, and § 601.12(f)(3), we estimate that approximately 275 NDA applicants, 275 ANDA applicants, and 75 BLA applicants (respondents) submit annual reports to us annually. We also estimate that each NDA applicant submits to us approximately 9.45 annual reports, each ANDA applicant submits approximately 16.18 annual reports, and each BLA applicant submits approximately 1 annual report each year. Further, we estimate that the total annual responses, i.e., the total number of annual reports submitted to us per year, will remain approximately 2,600 NDA annual reports, 4,450 ANDA annual reports, and 75 BLA annual reports.

Based on our experience with voluntary electronic submissions and our knowledge of the drug and biologic industries, we estimate that approximately 24 percent of NDA annual reports (624 NDA annual reports), 20 percent of ANDA annual reports (890 ANDA annual reports), and 24 percent of BLA annual reports (18 BLA annual reports), will already have the necessary labeling in an electronic

format that can be easily accessed and converted to a PDF file. As discussed above, we estimate that each NDA applicant submits to us approximately 9.45 annual reports, each ANDA applicant submits approximately 16.18 annual reports, and each BLA applicant submits approximately 1 annual report each year. Therefore, approximately 66 NDA applicants, 55 ANDA applicants, and 18 BLA applicants can easily access labeling in electronic form and convert it to a PDF file. For the applicants submitting these annual reports, we estimate that the hours per response, i.e., the additional time necessary for submission of the content of labeling in electronic format in the annual report, will be less than 15 minutes. Therefore, we estimate that respondents would spend approximately 383 hours per year submitting the content of labeling to us in these annual reports under the final rule.

As mentioned previously, we are adding a new category to the paperwork section to allow for proofreading the converted file of labeling that was previously submitted in annual reports in paper form (and not requiring any changes since it was last submitted), but is also maintained by the applicant in an electronic format. For applicants to include labeling content in their annual reports in electronic format, we estimate that approximately 36 percent of NDA annual reports (936 NDA annual reports), 30 percent of ANDA annual reports (1,335 ANDA annual reports), and 36 percent of BLA annual reports (27 BLA annual reports) will be submitted by applicants who previously submitted labeling in paper, but have such labeling available in electronic format. As discussed above, we estimate that each NDA applicant submits to us approximately 9.45 annual reports, each ANDA applicant submits approximately 16.18 annual reports, and each BLA applicant submits approximately 1 annual report each year. Therefore, under the final rule, approximately 99 NDA applicants, 83 ANDA applicants, and 27 BLA applicants would need additional time to proofread these annual reports. 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, will be approximately 5 hours. Therefore, we estimate that respondents would spend approximately 11,490 hours per year submitting the content of labeling to us in these annual reports under the final rule.

We recognize that annual reports for some drug and biological products, particularly older products for which labeling changes have not been made in

¹⁰ The numbers in this final rule have changed from the proposed rule because we have updated the numbers to be more current.