

several years, may require additional steps. For applicants to include labeling content in their annual reports in electronic format, we estimate that approximately 40 percent of NDA annual reports (1,040 NDA annual reports), 50 percent of ANDA annual reports (2,225 ANDA annual reports), and 40 percent of BLA annual reports (30 BLA annual reports) will be submitted by applicants who may need to access the labeling in their archives, put the content of labeling into an electronic format, and convert it to a PDF file. As discussed previously, 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 110 NDA applicants, 137 ANDA applicants, and 30 BLA applicants would need to put labeling content in an electronic format and convert it to a PDF file. 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 10 hours.¹¹ Therefore, we estimate that respondents would spend approximately 32,950 hours per year submitting the content of labeling to us in these annual reports under the final rule.

We estimate that in the first year, respondents will spend approximately 44,823 hours submitting the content of

labeling to us in annual reports under the final rule. This expenditure of time will only be necessary the first time that an annual report 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 annual reports 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 1,781 hours per year submitting the content of labeling in annual reports.

Description of Respondents: An applicant submitting an NDA, ANDA, BLA, supplement, or annual report to us for a drug or biological product.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Responses	Hours per Response	Total Hours
<i>Applications:</i> 314.50	83	1.02	85	.25	21
314.94	117	2.76	323	.25	81
601.14 (Applications submitted under § 601.2)	17	1	17	.25	4
Subtotal, applications					106
<i>Supplements:</i> 314.70 (Products not requiring additional steps for electronic submission)	167	1.52	254	.25	63
314.70 (Products requiring additional proofreading)	251	1.50	376	5	1,880
314.97 (Products not requiring additional steps for electronic submission)	61	6.50	396	.25	99
314.97(Products requiring additional proofreading)	91	6.50	604	5	3,020
601.14 (Supplements submitted under § 601.12(f)(1) and (f)(2))(Products not requiring additional steps for electronic submission)	8	1.25	10	.25	3
601.14 (Supplements submitted under § 601.12(f)(1) and (f)(2)) (Products requiring additional proofreading)	12	.83	10	5	50
Subtotal, supplements, year one					5,115
Subtotal, supplements, subsequent years ²					413
<i>Annual Reports:</i> 314.81 (Products not requiring additional steps for electronic submission)	66	9.45	624	.25	156
314.81 (Products requiring additional proofreading)	99	9.45	936	5	4,680

¹¹ The number increased from 8 hours to 10 hours to allow for additional time to proofread.