

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>—Continued

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Responses	Hours per Response	Total Hours
314.81 (Products requiring additional steps for electronic submission)	110	9.45	1,040	10	10,400
314.98 (Products not requiring additional steps for electronic submission)	55	16.18	890	.25	222
314.98 (Products requiring additional proofreading)	83	16.18	1,335	5	6,675
314.98 (Products requiring additional steps for electronic submission)	137	16.18	2,225	10	22,250
601.14 (Annual reports submitted under § 601.12(f)(3) not requiring additional steps for electronic submission)	18	1	18	.25	5
601.14 Annual reports submitted under § 601.12(f)(3) (Products requiring additional proofreading)	27	1	27	5	135
601.14 (Annual reports submitted under § 601.12(f)(3) requiring additional steps for electronic submission)	30	1	30	10	300
Subtotal, annual reports, year one					44,823
Subtotal, annual reports, subsequent years <sup>3</sup>					1,781
Total, year one					50,044
Total, subsequent years <sup>3</sup>					2,300

<sup>1</sup> There are one-time capital costs to: (1) Acquire computer software; (2) train employees to use the software; and (3) convert certain labeling to an electronic format. These costs are estimated to be about \$2.3 million (see section VIII of this document). There are no operating or maintenance costs associated with this collection of information.

<sup>2</sup> We estimate that for certain annual reports, respondents will spend 5 hours per response in the first year. We estimate that in subsequent years respondents will spend less than 15 minutes per response for all supplements.

<sup>3</sup> We estimate that for certain annual reports, respondents will spend either 5 or 10 hours per response in the first year. We estimate that in subsequent years respondents will spend less than 15 minutes per response for all annual reports.

In compliance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted a copy of this rule to OMB for its review and approval of these information collections.

The information collection provisions in this final rule have been approved under OMB control number 0910–0530. This approval expires on November 30, 2006. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the information collection displays a currently valid OMB control number.

#### VI. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment

nor an environmental impact statement is required.

#### VII. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

#### VIII. Analysis of Economic Impacts

We have examined the impacts of this final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule may have a significant economic impact on a substantial number of small entities, an agency must consider alternatives that would minimize the economic impact of the rule on small entities. Section 202(a) of the Unfunded