

The burden for learning the regulatory requirements of this proposed recordkeeping rule may be shared by firms that also need to learn the regulatory requirements of the proposed rule entitled "Registration of Food Facilities" (68 FR 5378, February 3, 2003). The learning burden presented in Table 44 of this document includes the total number of hours needed to learn and understand the records required for compliance. This is a one-time burden that covered firms will incur in the first year following enactment of the final rule.

The records redesign burden presented in Table 44 of this document reflects the burden that some firms will incur by adding a limited amount of new information to their records. Some firms will not already be keeping the

required information in a readily accessible form. The records redesign burden includes labor and capital costs associated with modifying existing forms so that they are better suited to meet the recordkeeping requirements. This is assumed to be a one-time burden incurred by each covered firm in the first and second years following implementation of the final rule.

The records access preparation burden presented in Table 44 of this document reflects the burden of preparing a plan for modifying current business practices in order to be able to respond to an FDA records request in the 4-hour or 8-hour required timeframe. The estimate of the records access planning burden is a one-time burden that would be incurred in the first and second years following

enactment of the final rule. We assume that this burden will be incurred by each facility.

FDA expects that personnel at most facilities will incur a records maintenance burden due to collecting, recording, and checking for accuracy the limited amount of additional information required by the proposed rule. The burden from this activity is reported in table 45 of this document and is assumed to be incurred by all facilities in each subsequent year following enactment of the final rule. Finally, new firms are assumed to incur burdens from learning and records access preparation in each subsequent year following enactment of the final rule. These burdens for new firms are reported in table 44 of this document.

TABLE 44.—ESTIMATED ANNUAL RECORDKEEPING BURDEN—ONE-TIME BURDEN<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Capital Costs	Total Hours
1.337, 1.345, and 1.352, (Learning)	804,319	1	804,319	6.853		5,512,000
1.337, 1.345, and 1.352, (Redesign)	278,858	1	278,858	29.607	\$130,582,000	8,256,000
1.361 (Access Preparation)	552,630	1	552,630	5.626		3,109,000
Total						16,877,000

<sup>1</sup> There are no operating and maintenance costs associated with this collection of information.

TABLE 45.—ESTIMATED ANNUAL RECORDKEEPING BURDEN—SUBSEQUENT YEARS<sup>1</sup>

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Total Hours
1.337, 1.345, and 1.352 (Additional Records Maintenance)	772,410	1	772,410	10.625	8,207,000
1.337, 1.345, and 1.352, (Learning for New Firms)	80,432	1	80,432	6.853	551,000
1.361 (Access Preparation for New Firms)	55,263	1	55,263	5.626	311,000
Total					9,069,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection to OMB (see ADDRESSES).

## V. Analysis of Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded 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.

## VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed 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 tentatively concludes that the

proposed 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.

## VII. Comments

Interested persons may submit to the Dockets Management Branch (see ADDRESSES) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the