receive, or hold food contact substances other than the finished container that directly contacts the food, and who manufacture or process the finished container that directly contacts the food, as estimated by the number of applicable facilities, is small. Although relaxing requirements for these persons may expose a ''soft target'' for intentional contamination, the probability of foodborne illness from unintentionally contaminated food contact substance and finished container material is low. Furthermore, the likelihood of needing records from food contact substance and finished container facilities during traceback investigations is also low. When compared to the other issues considered for the final rule, relaxing the requirements for these persons ranks only seventh in the reductions in benefits relative to the baseline.

The reduction in benefits from relaxing the requirement to access records within 24 hours from 4- and 8-hour requirement would be substantial. We estimate that relaxing the records access requirement would increase the amount of time for any preventive action to be taken during a traceback investigation by about 5 days relative to the baseline, if all persons subject to an access request took the full 24 hours to respond. The loss of time relative to the baseline would limit the preventive benefits for 15 percent to 18 percent of outbreaks. Relaxing the record access requirement from 4 and 8 hours, to within 24 hours ranks second in reductions in benefits relative to the baseline.

The reduced benefits from extending the compliance period by 6 months for each person subject to the final rule are a twofold increase in the number of outbreak victims relative to the baseline in the first year only. Baseline benefits reduce the impact of 15 percent to 18 percent of outbreaks and eliminate the problem of prematurely terminated investigations because of poor records quality (i.e., about 10 percent of the total number of traceback

investigations estimated from FDA outbreak investigation information). Extending the compliance dates by 6 months ranks sixth in the reductions in benefits relative to the baseline.

We estimate that allowing transporters to comply with this final rule by complying with existing requirements (e.g., records already required by FMCSA) will have a negligible impact on the benefits relative to that from the more comprehensive requirements of the proposal. Option 7 in table 16 of this document incorporates a 24-hour access provision, 6, 12, and 24 month retention requirements, extension of the compliance dates, and adjusted recordkeeping requirements for transporters based on existing requirements. In table 18 of this document, the costs and benefits of the final rule are compared with those from the adjusted comprehensive coverage of option 7 in table 16 of this document.

TABLE 16.—COSTS AND REDUCTIONS IN FOOD SAFETY BENEFITS FOR CHANGES BASED ON COMMENTS

	Policy Option (in Terms of the Baseline)	Cost (7% Discount)	Cost (3% Discount)	Reduction in Benefits Relative to the Baseline
Baseline[1]: Proposed rule except requirement for all records to contain lot codes is relaxed.	$4.0 billion	$5.27 billion		
(1) Baseline except existing interstate transporter requirements are sufficient.	$3.78 billion	$4.97 billion	No reduction[2]	1
(2) Baseline except retention of 6, 12, and 24 months per NIST standards	$4.0 billion	$5.27 billion	Negligible reduction	2
(3) Baseline except food contact entities are excluded.[3]	$3.92 billion	$5.16 billion	Exclude 37,000 facilities near the top of supply chain. Low risk of contamination and low risk of loss of the paper trail.	3
(4) Baseline except compliance dates are extended by 6 months.	$3.73 billion	$5.10 billion	An estimated one-time, two-fold increase in the number of victims compared with the baseline in the first year only.	4
(5) Baseline except foreign facilities are excluded.	$3.23 billion	$4.26 billion	Exclude 225,000 facilities near the beginning of the supply chain. Very high cost of enforcement and access.	5
(6) Baseline except relax records access from 4 and 8 hours, to 24 hours.	$3.74 billion	$4.95 billion	Adds a maximum of about 5 days to the time for preventive action during an outbreak.	6

TABLE 16.—COSTS AND REDUCTIONS IN FOOD SAFETY BENEFITS FOR CHANGES BASED ON COMMENTS—Continued

	Policy Option (in Terms of the Baseline)	Cost (7% Discount)	Cost (3% Discount)	Reduction in Benefits Relative to the Baseline
(7) Adjusted comprehensive coverage	$2.59 billion	$3.57 billion	Incorporates all policy options and adjusted numbers of facilities	

[1] Note that option 1 is used as the baseline in the descriptions of all other options. The variation of the proposed rule with the relaxed lot code requirements is used as the baseline in this table because the high cost of requiring lot codes on all records ($16.58 billion) is overwhelming. While the reduction in benefits from relaxing the lot code requirements is also large, we thought that the inclusion of that option in this table would confuse the presentation and add little practical value to the policy analysis.

[2] Because this chart only reflects food safety, it does not include classified food security scenarios which envision intrastate shipments being targeted for tampering.

[3] This option overstates the cost reduction from provisions in the final rule that exclude food contact substance entities since it assumes that they will not have to incur learning, records redesign, and additional records maintenance costs. In the final rule these entities will incur learning costs since they will still be subject to access requirements for records that they keep during the course of normal business activity.

We constructed the policy options reported in the following tables to provide a range of net benefit and cost effectiveness measures for alternative coverage options. The records access, retention, and compliance date provisions, as well as the requirements for transporters for all options reported in the following tables, are the same as those reported for option 7 in the previous table. In addition, coverage for the option entitled ''all entities'' is the same as that for option 7 in the previous table. Persons handling the finished container that contacts food are excluded from all of the following coverage options for the policy reasons stated previously. However, while persons handling the finished container that contacts food other than those who place food directly in contact with the finished container, are not required to establish and maintain records in the final rule, they are required to provide access to FDA to existing records if the conditions for access are satisfied. This requirement is implicit in all of the options with different coverage reported in the following tables.

TABLE 17.—COVERAGE OF DIFFERENT POLICY OPTIONS

	Grocery Outlets	Importers and Wholesalers	Manufacturers	Mixed-Type Facilities	Warehouses	Transporters
Option						
Adjusted Comprehensive	All	All	All	All	All	All
A		All				
B	All					
C		All	All			

TABLE 17.—COVERAGE OF DIFFERENT POLICY OPTIONS—Continued

	Grocery Outlets	Importers and Wholesalers	Manufacturers	Mixed-Type Facilities	Warehouses	Transporters
D		All	All	All		
E		All	All	All	All	
F		All	All	All	All	All
G (final rule)	Exclude very small	All	All	All	All	All
H	Exclude very small	Exclude very small	Exclude very small	Exclude very small	Exclude very small	Exclude very small
I	Exclude very small	All	All	All	All	Only interstate

Note: Very small firms are defined as those with fewer than 10 full-time equivalent employees.

In the following table, costs, food safety benefits, and cost effectiveness measures are reported for each of the coverage options described in the above table, and the final rule. Costs are reported in terms of annualized costs and incremental costs using a 7-percent discount rate over a 20-year horizon. Benefits are reported in terms of the annual number of food safety illnesses averted (reported and unreported), and the incremental number of illnesses averted. The estimates of the numbers of averted illnesses should be interpreted as minimum values because they relate to only the food safety benefits; bioterrorism considerations are not incorporated into the estimates. Cost effectiveness measures are in terms of the incremental costs per averted illness, and the average cost per averted illness.

The incremental cost per averted illness is used to measure the relative cost effectiveness of an option when compared with successively more stringent requirements. It is computed by dividing the incremental costs from the option by the incremental benefits. Since option H averts a larger number of illnesses at lower cost then options A through F, option H dominates the other options and they can be eliminated from further consideration in an incremental cost effectiveness analysis. Thus, the cells for computing the incremental costs per averted illness for those options are left blank in table 18 of this document. Similarly, through the principle of weak (or extended)

dominance, option I can be eliminated from the incremental cost effectiveness analysis. (For a full discussion of extended dominance in cost-effectiveness analysis, see Gold, M.L., J.E. Siegel, L.B. Russell, and M.C. Weinstein, ‘‘ Cost Effectiveness in Health and Medicine: The Report of the Panel on Cost-Effectiveness in Health and Medicine, Oxford University Press,’’ New York, p. 286, 1996). Consequently, only options H, the final rule, and the adjusted comprehensive coverage are used to measure the incremental cost effectiveness. We assume that bioterrorism considerations would not alter the relative order of the number of illnesses averted across all options.

The average costs per averted illness reported in table 18 of this document are calculated by dividing the annualized costs by the total number of illnesses averted for each option. The average costs per averted illness is the cost-effectiveness of each option relative to the baseline. For the final rule, the average cost-effectiveness expressed in costs per illness prevented is $110,000 discounted at 7 percent and $108,000 discounted at 3 percent.

TABLE 18.—COSTS, FOOD SAFETY BENEFITS, AND COST EFFECTIVENESS OF ALTERNATIVE COVERAGE OPTIONS

	Costs		Benefits		Cost Effectiveness	
	Annualized Costs	Incremental Cost	Illnesses averted	Incremental Benefit	Incremental Cost per Averted Illness	Average Cost per Averted Illness
Option A	$40,975,852		245			$167,248
Option C	$56,753,102		316			$179,598
Option D	$67,712,296		355			$190,739
Option E	$69,902,094		359			$194,713
Option B	$135,636,340		572			$237,126
Option F	$119,792,995		621			$192,903
Option H	$30,610,378	$30,610,378	1,067	1,067	$28,688	$28,688
Option I	$106,138,020		1,072			$99,009
Final Rule	$132,750,092	$102,139,714	1,204	137	$745,545	$110,258
Adjusted Comprehen-sive	$244,134,086	$111,383,994	1,282	78	$1,428,000	$190,432

The distribution of the number of illnesses averted due to faster traceback investigations and more successfully completed traceback investigations for each policy option are also reported in the following tables. Of the 800 annual

food safety illnesses averted due to improved recordkeeping practices, about 600 can be attributed to more successfully completed tracebacks, and about 200 from faster tracebacks. The sum of averted illnesses from faster tracebacks, plus that from more successfully completed tracebacks may differ from that reported in the table of totals because of rounding in the computations.

TABLE 19.—ALL AVERTED (REPORTED AND UNREPORTED) FOOD SAFETY ILLNESSES PER YEAR

	Mean	Low	High
Adjusted Comprehensive	1,282	0	6,400
Option A	245	0	1,079
Option B	572	0	2,660
Option C	316	0	1,452
Option D	355	0	1,612
Option E	359	0	1,750
Option F	621	0	2,846
Final Rule	1,204	0	6,061
Option H	1,067	0	5,372
Option I	1,072	0	5,504

TABLE 20.—AVERTED ANNUAL FOOD SAFETY ILLNESSES FROM FASTER TRACEBACK INVESTIGATIONS

	Mean	Low	High
Adjusted Comprehensive	451	0	2,692
Option A	83	0	513
Option B	206	0	1,278
Option C	111	0	691
Option D	122	0	755
Option E	124	0	763
Option F	184	0	1,078
Final Rule	425	0	2,532
Option H	387	0	2,307
Option I	396	0	2,414

TABLE 21.—AVERTED ANNUAL FOOD SAFETY ILLNESSES FROM MORE SUCCESSFULLY COMPLETED TRACEBACKS

	Mean	Low	High
Adjusted Comprehensive	826	0	3,024
Option A	161	0	605
Option B	364	0	1,296
Option C	203	0	778
Option D	232	0	864
Option E	234	0	864
Option F	434	0	1,728
Final Rule	775	0	2,592

TABLE 21.—AVERTED ANNUAL FOOD SAFETY ILLNESSES FROM MORE SUCCESSFULLY COMPLETED TRACEBACKS—Continued

	Mean	Low	High
Option H	676	0	2,592
Option I	673	0	2,592

The next table shows the food safety benefits as the number of averted illnesses valued by the low, middle, and high cost of illness estimates, and for the $5 million and $6.5 million estimates of the value of a statistical life. These are estimated annual food safety benefits and should be interpreted as minimum benefits from this final rule because food security benefits are not included.

TABLE 22.—VALUE OF AVERTED FOOD SAFETY ILLNESSES FOR THE FINAL RULE

	Low[2]	Medium[3]	High[4]
VSL[1] = $5 million	$7,388,685	$15,905,182	$24,421,229
VSL = $6.5 million	$8,199,494	$16,715,991	$25,232,038

[1] Value of a statistical life used to value the averted deaths.
[2] A value of $100,000 was used to value a year in good health.
[3] A value of $300,000 was used to value a year in good health.
[4] A value of $500,000 was used to value a year in good health.

V. Final Regulatory Flexibility Analysis

FDA has examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would lessen the economic effect of the final rule on small entities. FDA finds that this final rule may have a significant economic impact on a substantial number of small entities.

We estimate that more than 75 percent of all businesses covered by this final rule are small or very small. The undiscounted per-facility costs for small and very small businesses are reported in the following table. Costs for learning and records redesign are one-time costs incurred in the first 2 years following publication of the final rule. Additional records maintenance costs are incurred

each year following publication of the final rule beginning in the second year for large and small firms, and in the third year for very small firms.

TABLE 23.—ESTIMATED PER FACILITY RECORDKEEPING COSTS

21 CFR Section	Costs
1.337, 1.345, and 1.352 (learning)	$120.00
1.337, 1.345, and 1.352 (records redesign)	$411.00
1.337, 1.345, and 1.352 (additional records maintenance)	$219.00

Comments Summary

Comments cover topics such as reasons why staggering compliance dates will not achieve regulatory flexibility objectives, suggestions of regulatory alternatives that would achieve regulatory flexibility objectives, appeals to consider the cumulative costs of all four bioterrorism regulations together when considering the impact on small businesses, appeals for exclusion of certain categories of small businesses, as well as other general topics. The different categories of comments are summarized in the following paragraphs.

(Comment 214) One comment finds the definition of ''small business'' uncertain and asks whether it is based on either the number of employees at a firm or the number of employees at a facility.

(Response) The U.S. Small Business Administration (SBA) establishes small business definitions (or size standards) by industry (Ref. 28). The most common SBA size standard applicable to manufacturers covered by this final rule is 500 employees. Other pertinent SBA size standards include 100 employees for wholesale distributors, $21.5 million in receipts for transporters, and $6 million or $23 million in receipts for retailers, depending on the type of store. After discussions with the SBA, we define a small business in the food industry as having more than 10 and fewer than 500 full-time equivalent employees, and we define very small firms as having 10 or fewer full-time equivalent employees.

Firm size, rather than facility size, is used in the cost estimates for regulatory flexibility purposes whenever the data permit. For purpose of the compliance dates, the firm size governs. For purpose of the retail exclusion, the number of employees at the facility applies.

(Comment 215) Several comments suggest that the recordkeeping requirements are so onerous that compliance periods should be extended to as many as 7 years.

(Response) In the PRIA, FDA assumed that the recordkeeping provisions required a limited amount of additional information over current business practices. Comments suggest that this may not be true for certain provisions. In the final rule, we have relaxed some of the more costly provisions, such as the requirement for records to contain lot code information for all persons subject to the final rule, and we have relaxed the records access requirement to 24 hours. We have also revised the requirements applicable to transporters so that they have multiple options for complying with the final rule. These modifications should reduce the costs of compliance for small businesses. In addition, we have extended the compliance dates of the final rule by 6 months to 12, 18, and 24 months for large, small, and very small businesses. The extension should further reduce the costs of compliance with the final rule because the costs of the required changes in records quality and records access fall as compliance time increases. Moreover, given the purpose of the Bioterrorism Act, FDA believes a 7-year compliance period is excessive.

(Comment 216) One comment states that large carriers account for only 0.28 percent of all carriers and that 0.28 percent of all carriers should not be unfairly burdened to comply with regulations 1 year before the rest. Another comment states that across-the-board compliance dates of 18 months better

serves the purposes of the Bioterrorism Act, because it reflects the large volume of food that moves through big business.

(Response) The Regulatory Flexibility Act requires that special consideration be given to small businesses when such flexibility does not compromise the efficacy of the regulation. In the PRIA, FDA considered several other potential flexibility options and found that the policy of staggering the compliance dates and exempting very small retailers were the only ones that did not appreciably compromise the effectiveness of the regulation.

(Comment 217) Several comments state that large businesses would likely pass the costs of the regulation on to smaller firms. In addition, the proposed regulatory flexibility from staggered compliance dates would largely be ineffective, because large businesses will require their small suppliers to comply with the regulation to ensure their own compliance. Another comment suggests extending the compliance dates to 18 months for large businesses and 36 months to small businesses but acknowledged that staggering compliance dates would complicate business practices.

(Response) FDA acknowledges the difficulties in addressing regulatory flexibility considerations with staggered compliance dates. Nevertheless, FDA has decided that staggering the compliance dates is a viable mechanism to address regulatory flexibility considerations without compromising the effectiveness of the regulation as intended by Congress when it enacted section 306 of the Bioterrorism Act. However, to address the concerns expressed by these comments without compromising the effectiveness of the regulation, in the final rule compliance dates for all size businesses have been extended by 6 months to 12 months for large, 18 months for small, and 24 months for very small businesses. FDA further notes that small and very small businesses are

not required by FDA to comply earlier than these timeframes even if they are doing business with larger businesses that have earlier compliance dates.

(Comment 218) At least one comment suggests that requiring the same compliance date for all firms and excluding small businesses from complying with the regulation compromises the effectiveness of the regulation due to breaks in the recordkeeping chain during traceback investigations. Such a compromise is contrary to the intent of the Regulatory Flexibility Act.

(Response) In the PRIA, FDA considered three regulatory flexibility options: (1) Exempting small business from all regulatory requirements, (2) offering small business exemptions from parts of the regulation, and (3) specifying longer effective compliance dates for small businesses. We found that specifying longer compliance dates for small businesses was one option that would not appreciably compromise the purpose of the regulation.

(Comment 219) Several comments state that the 4 and 8 hour provision for records access is more onerous for small businesses and suggest either flexibility in the extent of the records to be made available in that time period for small businesses, or extending the records access time requirements for small businesses. One comment suggests that the rule requires firms to keep more records than is necessary and that FDA should consider relaxing the level of detail in the small business records required to be made available in the 4 and 8-hour records access times. One comment states that the burden on a small firm from devoting a single employee, who generally performs multiple tasks, to accessing requested records is greater than that on a large firm devoting an employee who may generally perform only one task.

(Response) The proposed rule required large and small firms to provide access to records up to 4 hours after a request made during business hours,

and up to 8 hours after a request made after business hours. FDA's current experience is that access to records generally takes 2 to 3 days and the requirements in the regulation will considerably increase the speed of traceback investigations. To acknowledge the concerns addressed by these comments, FDA has relaxed the records access requirement to as soon as possible, but within 24 hours. This longer requirement should provide regulatory relief to small businesses; however, FDA reiterates that it expects all businesses to provide access as soon as possible, given that an access request would only be made in a food-related emergency.

(Comment 220) Several comments request an exemption for some specific categories of small business, because they believe the estimated costs of compliance for small businesses are inadequate. Furthermore, one comment states that the regulatory flexibility provisions in the proposed rule did not satisfy SBREFA obligations.

(Response) FDA addresses SBREFA's regulatory flexibility issues by exempting very small retailers, and by staggering compliance dates so that small and very small businesses would have 18 and 24 months to comply with the regulation. Because food in commerce generally passes through at least one small business before reaching consumers, excluding small businesses in every sector from compliance with the regulation would risk severely compromising the effectiveness of the regulation due to breaks in the recordkeeping chain during traceback investigations.

(Comment 221) Some comments argue that FDA should address the relatively large burden on small businesses due to the cumulative cost of the four bioterrorism regulations when considered together. The comments state that the proposed registration rule estimated that approximately 16 percent of

foreign businesses might cease to export to the United States as a result of that rule. The comments note that this figure was used in the sensitivity analysis in the proposed recordkeeping rule to estimate the costs of the rule with 16 percent fewer foreign facilities. However, the comments stated that FDA did not consider the costs of all the bioterrorism regulations combined on small (or other) businesses.

(Response) The cumulative costs of multiple regulations are rarely considered in regulatory impact analyses. However, costs of the other three regulations were analyzed in their respective regulatory impact analyses. To estimate the cumulative costs of the regulation one could add together the costs determined for all four regulations.

VI. Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires cost-benefit and other analyses before any rule making if the rule will include a ''Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' The current inflation-adjusted statutory threshold is $112,300,000. FDA has determined that this final rule does constitute a significant rule under the Unfunded Mandates Reform Act.

Most of the requirements of the Unfunded Mandates have been fulfilled in the Executive Order 12866 analysis in the PRIA. The requirements under the Unfunded Mandates Act of 1995 include assessing the rule's effects on future costs; productivity; particular regions, communities, or industrial sectors; economic growth; full employment; job creation; and exports.

Future Costs

The future costs from the recordkeeping rule include the recurring costs, which reach their long-term value in the third year after promulgation of the final rule. These costs will be incurred by all domestic facilities that manufacture, process, pack, transport, distribute, receive, hold, or import food except very small retail facilities.

Recurring costs from collecting new information as well as the learning costs for new entrants will be incurred in each future year. An hourly burden of 30 minutes a week was estimated for the additional monitoring and recordkeeping that will be required from this final rule. This hourly burden estimate was modified for convenience stores to allow for structural differences assumed in their operations. Refer to the PRIA for a fuller illustration of the future costs of the final rule.

Table 24.—Future Costs

	Mean	Low	High
Year 3 and later years	$123,209,200	$121,980,000	$125,788,000

Particular Regions, Communities, or Industrial Sectors

The costs of the establishment and maintenance of records will be shared among all domestic manufacturers, processors, packers, transporters, receivers, holders, and importers of food, except very small retail facilities that are exempted from the final rule. The higher costs incurred by domestic suppliers as a result of these regulations will mostly be passed on to consumers in the form of higher food prices. Because consumer demand for food is highly inelastic, almost all of the higher costs incurred by food suppliers will be passed on to consumers. Consequently, higher food prices will reduce real incomes for all consumers. However, we believe that the benefits from these regulations will justify the reduction in real incomes. These benefits are measured as an improved ability by the FDA to respond to and contain threats

of serious adverse health consequences from accidental or deliberate contamination of food.

National Productivity, Economic Growth, Job Creation, and Full Employment

Although this regulation is costly, we do not expect it to substantially affect national productivity, growth, jobs, or full employment. The total costs will be small relative to the economy, and will be offset by benefits. The improved ability to respond to, and contain, serious adverse health consequences means less illness and fewer sick days taken by employees, and lower adjustment costs by firms that would otherwise need to hire replacement employees.

Exports

This rule requires additional records to be kept throughout the production and distribution chain for food. The additional recordkeeping costs will increase the total costs of production and distribution for all of the regulated products, including products sold within the United States and across national borders. These increased costs will be largely passed on to consumers in the form of higher prices, which will tend to reduce the quantity demanded of the regulated products. The increased prices of United States exports could reduce the quantity of United States exports demanded, particularly in comparison with exports from countries that do not implement similar recordkeeping regulations. We expect this effect to be insignificant, because under the final rule, the increases in the price of United States exports (and resulting decreases in quantity demanded) will be quite small.

VII. SBREFA

SBREFA (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more

of the following: an annual effect on the economy of $100 million or more; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with SBREFA, OMB has determined that this final rule is a major rule for the purpose of congressional review.

VIII. Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject to review by OMB under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection requirement are shown below with an estimate of the annual recordkeeping burden. Included in the 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: Establishment and Maintenance of Records

Description: The Bioterrorism Act contains a provision authorizing the Secretary to establish requirements regarding the establishment and maintenance of records by persons who manufacture, process, pack, transport, distribute, receive, hold, or import food which are needed to allow the Secretary to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequence or death to humans or animals.

Description of Respondents: Persons that manufacture, process, pack, hold, receive, distribute, transport, or import food in the United States are required to establish and maintain records, including persons that engage in both interstate and intrastate commerce. FDA received several comments about the hourly burden imposed by the rule on respondents.

(Comment 222) One comment states that the cumulative effect of the regulation is a staggering amount of required paperwork that needs to be organized and made available.

(Response) This comment is not directly responding to any specific request for comments but is a general comment. The duplication of records is unnecessary as long as existing records contain all of the required information. In this analysis we use the FDA small business model to calculate the effects on small businesses using the difference between revenues and variable costs as the metric. We incorporated both the one-time costs and the recurring costs to compute the effects on small businesses. The effects were computed for firms in the dietary supplements industry, candy manufacturing, and the ready-to-eat food manufacturing industry, including firms that manufacture breakfast cereals, beverages, canned foods, baked items and breads, and dressings and sauces. While these firms do not represent every category of food establishment covered by this final rule, they do reflect a large number of firms in the food industry, including manufacturers, input suppliers, and distributors. FDA assumes that the cost and revenue structures of firms not explicitly included in the computation of the model do not differ substantially from those that are included.

Consistent with FDA's assumption that the rule will require only small changes to current recordkeeping practices, the findings from the small

business model indicate that virtually no small businesses will incur negative cash flows as a result of this rule. The percentages of firms predicted to incur negative cash flows are range from 0.2 percent to a high of 1.9 percent for the ready-to-eat food manufacturing industry. These findings strongly suggest that very few firms, if any, will be driven from business as a result of this rule. In the Unfunded Mandates section of the PRIA, we also consider the impacts of the proposal on food prices and conclude that any effect would be negligible.

(Comment 223) One comment states that the PRA was adopted to prevent the burden of collecting unnecessary information that has little practical utility or benefit. The comment further states that FDA needs to realign the benefits with the costs of the regulation.

(Response) This is a response to the request for comments on whether the information required in the proposal would have any practical utility. Compared with the description of the costs in the proposal, the benefits were not as well defined. In the final rule, the benefits of each provision are more clearly identified, which facilitates greater realignment of costs with the benefits of the regulation. As stated previously, however, the benefits are underestimated because they only consider food safety concerns and do not address food security concerns, which are based on classified information.

(Comment 224) One comment suggests that FDA should reduce the paperwork burden by integrating the paperwork requirements from this regulation with current U.S. CBP process so that only one form needs to be completed.

(Response) The final recordkeeping regulation excludes all foreign persons, except for foreign persons who transport food in the United States

so that many foreign persons do not have to establish or maintain records. Moreover, neither the proposed nor final rules specify the form or format of required records. Accordingly, existing records used for U.S. CBP purposes may be used if they contain all of the information required by this final rule and are retained for the required time period.

Burden: FDA estimates that the paperwork burden of this final rule will be incurred by approximately 707,672 facilities owned by 581,943 firms. This number includes domestic facilities that manufacture, process, transport, distribute, pack, receive, hold, or import food as well as foreign persons who transport food in the United States. Some of the recordkeeping burden will be incurred at the firm level and some of the burden will be incurred at the facility level.

The recordkeeping burden for §§ 1.337, 1.345, and 1.352 of this final rule includes learning about the regulation requirements, the redesign of records, and records maintenance including information collection for these records. 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 registration interim final rule (68 FR 58894). The learning burden presented in table 25 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 issuance of the final rule.

The records redesign burden presented in table 25 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.

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 25 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 in each subsequent year following enactment of the final rule. These burdens for new firms are reported in table 26 of this document.

TABLE 25.—ESTIMATED ANNUAL RECORDKEEPING BURDEN—FIRST AND SECOND YEARS[1]

21 CFR Section	No. of Record keepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Capital Costs	Total Hours
1.337, 1.345, and 1.352 (learning)	707,672	1	707,672	4.790		3,390,000
1.337, 1.345, and 1.352 (redesign)	150,358	1	150,358	29.084	$70,409,000	4,373,000
Total						7,763,000

[1] There are no operating and maintenance costs associated with this collection of information.

TABLE 26.—ESTIMATED ANNUAL RECORDKEEPING BURDEN—SUBSEQUENT YEARS[1]

21 CFR Section	No. of Record Keepers	Annual Frequency per Record	Total Annual Records	Hours per Record	Total Hours
1.337, 1.345, and 1.352 (additional records maintenance)	379,493	1	379,493	13.228	5,020,000
1.337, 1.345, and 1.352 (learning for new firms)	70,767	1	70,767	4.790	339,000
Total					5,359,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The information collection provisions of this final rule have been submitted to OMB for review.

Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a

collection of information unless it displays a currently valid OMB control number.

IX. 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.

X. Federalism

FDA has analyzed this final 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 concludes that the final 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.

XI. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but we are not responsible for subsequent changes to the nonFDA Web sites after this document publishes in the **Federal Register**.)

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List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 11

Administrative practice and procedure, Computer technology, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 1 and 11 are amended as follows:

PART 1—GENERAL ENFORCEMENT REGULATIONS

■ 1. The authority citation for 21 CFR part 1 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 19 U.S.C. 1490, 1491; 21 U.S.C. 321, 331, 332, 333, 334, 335a, 343, 350c, 350d, 352, 355, 360b, 362, 371, 374, 381, 382, 393; 42 U.S.C. 216, 241, 243, 262, 264.

■ 2. New subpart J (§§ 1.326 through 1.368) is added to part 1 to read as follows:

Subpart J—Establishment, Maintenance, and Availability of Records

General Provisions

Sec.

Requirements for Nontransporters to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Previous Sources of Food

Requirements for Nontransporters to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Subsequent Recipients of Food

Requirements for Transporters to Establish and Maintain Records

General Requirements

Subpart J—Establishment, Maintenance, and Availability of Records

General Provisions

§ 1.326 Who is subject to this subpart?

(a) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States are subject to the regulations in this subpart, unless you qualify for one of the exclusions in § 1.327. If you conduct more than one type of activity at a location, you are required to keep records with respect to those activities covered by this subpart, but are not required by this subpart to keep records with respect to activities that fall within one of the exclusions in § 1.327.

(b) Persons subject to the regulations in this subpart must keep records whether or not the food is being offered for or enters interstate commerce.

§ 1.327 Who is excluded from all or part of the regulations in this subpart?

(a) Farms are excluded from all of the requirements in this subpart.

(b) Restaurants are excluded from all of the requirements in this subpart. A restaurant/retail facility is excluded from all of the requirements in this subpart if its sales of food it prepares and sells to consumers for immediate consumption are more than 90 percent of its total food sales.

(c) Fishing vessels, including those that not only harvest and transport fish but also engage in practices such as heading, eviscerating, or freezing intended solely to prepare fish for holding on board a harvest vessel, are excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363. However,

those fishing vessels otherwise engaged in processing fish are subject to all of the requirements in this subpart. For the purposes of this section, ''processing'' means handling, storing, preparing, shucking, changing into different market forms, manufacturing, preserving, packing, labeling, dockside unloading, holding or heading, eviscerating, or freezing other than solely to prepare fish for holding on board a harvest vessel.

(d) Persons who distribute food directly to consumers are excluded from the requirements in § 1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients as to those transactions. The term ''consumers'' does not include businesses.

(e) Persons who operate retail food establishments that distribute food to persons who are not consumers are subject to all of the requirements in this subpart. However, the requirements in § 1.345 to establish and maintain records to identify the nontransporter and transporter immediate subsequent recipients that are not consumers applies as to those transactions only to the extent the information is reasonably available.

(1) For purposes of this section, retail food establishment is defined to mean an establishment that sells food products directly to consumers as its primary function. The term ''consumers'' does not include businesses.

(2) A retail food establishment may manufacture/process, pack, or hold food if the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers.

(3) A retail food establishment's primary function is to sell food directly to consumers if the annual monetary value of sales of food products directly

to consumers exceeds the annual monetary value of sales of food products to all other buyers.

(4) A ''retail food establishment'' includes grocery stores, convenience stores, and vending machine locations.

(f) Retail food establishments that employ 10 or fewer full-time equivalent employees are excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363. The exclusion is based on the number of full-time equivalent employees at each retail food establishment and not the entire business, which may own numerous retail stores.

(g) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food in the United States that is within the exclusive jurisdiction of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*) are excluded from all of the requirements in this subpart with respect to that food while it is under the exclusive jurisdiction of USDA.

(h) Foreign persons, except for foreign persons who transport food in the United States, are excluded from all of the requirements of this subpart.

(i) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food are subject to §§ 1.361 and 1.363 with respect to its packaging (the outer packaging of food that bears the label and does not contact the food). All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import packaging are excluded from all of the requirements of this subpart.

(j) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food contact substances other than the finished container that

directly contacts food are excluded from all of the requirements of this subpart, except §§ 1.361 and 1.363.

(k) Persons who place food directly in contact with its finished container are subject to all of the requirements of this subpart as to the finished container that directly contacts that food. All other persons who manufacture, process, pack, transport, distribute, receive, hold, or import the finished container that directly contacts the food are excluded from the requirements of this subpart as to the finished container, except §§ 1.361 and 1.363.

(l) Nonprofit food establishments are excluded from all of the requirements in this subpart, except §§ 1.361 and 1.363.

(m) Persons who manufacture, process, pack, transport, distribute, receive, hold, or import food for personal consumption are excluded from all of the requirements of this subpart.

(n) Persons who receive or hold food on behalf of specific individual consumers and who are not also parties to the transaction and who are not in the business of distributing food are excluded from all of the requirements of this subpart.

§ 1.328 What definitions apply to this subpart?

The definitions of terms in section 201 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321) apply to such terms when used in this subpart. In addition, for the purposes of this subpart:

Act means the Federal Food, Drug, and Cosmetic Act.

Farm means a facility in one general physical location devoted to the growing and harvesting of crops, the raising of animals (including seafood), or both. Washing, trimming of outer leaves, and cooling produce are considered part of harvesting. The term ‘‘farm’’ includes:

(1) Facilities that pack or hold food, provided that all food used in such activities is grown, raised, or consumed on that farm or another farm under the same ownership; and

(2) Facilities that manufacture/process food, provided that all food used in such activities is consumed on that farm or another farm under the same ownership.

Food has the meaning given in section 201(f) of the act. Examples of food include, but are not limited to fruits; vegetables; fish; dairy products; eggs; raw agricultural commodities for use as food or as components of food; animal feed, including pet food; food and feed ingredients and additives, including substances that migrate into food from the finished container and other articles that contact food; dietary supplements and dietary ingredients; infant formula; beverages, including alcoholic beverages and bottled water; live food animals; bakery goods; snack foods; candy; and canned foods.

Full-time equivalent employee means all individuals employed by the person claiming the exemption. The number of full-time equivalent employees is determined by dividing the total number of hours of salary or wages paid directly to employees of the person and of all of its affiliates by the number of hours of work in 1 year, 2,080 hours (i.e., 40 hours x 52 weeks).

Holding means storage of food. Holding facilities include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.

Manufacturing/processing means making food from one or more ingredients, or synthesizing, preparing, treating, modifying, or manipulating food, including food crops or ingredients. Examples of manufacturing/processing activities are cutting, peeling, trimming, washing, waxing, eviscerating, rendering, cooking, baking, freezing, cooling, pasteurizing,

homogenizing, mixing, formulating, bottling, milling, grinding, extracting juice, distilling, labeling, or packaging.

Nonprofit food establishment means a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption by humans or animals in the United States. The term includes central food banks, soup kitchens, and nonprofit food delivery services. To be considered a nonprofit food establishment, the establishment must meet the terms of section 501(c)(3) of the U.S. Internal Revenue Code (26 U.S.C. 501(c)(3)).

Nontransporter means a person who owns food or who holds, manufactures, processes, packs, imports, receives, or distributes food for purposes other than transportation.

Nontransporter immediate previous source means a person that last had food before transferring it to another nontransporter.

Nontransporter immediate subsequent recipient means a nontransporter that acquires food from another nontransporter.

Packaging means the outer packaging of food that bears the label and does not contact the food. Packaging does not include food contact substances as they are defined in section 409(h)(6) of the act (21 U.S.C. 348(h)(6)).

Person includes individual, partnership, corporation, and association.

Recipe means the formula, including ingredients, quantities, and instructions, necessary to manufacture a food product. Because a recipe must have all three elements, a list of the ingredients used to manufacture a product without quantity information and manufacturing instructions is not a recipe.

Restaurant means a facility that prepares and sells food directly to consumers for immediate consumption. ''Restaurant'' does not include facilities that provide food to interstate conveyances, central kitchens, and

other similar facilities that do not prepare and serve food directly to consumers.

(1) Facilities in which food is directly provided to humans, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens, are restaurants.

(2) Pet shelters, kennels, and veterinary facilities in which food is directly provided to animals are restaurants.

Transporter means a person who has possession, custody, or control of an article of food in the United States for the sole purpose of transporting the food, whether by road, rail, water, or air. Transporter also includes a foreign person that transports food in the United States, regardless of whether that foreign person has possession, custody, or control of that food for the sole purpose of transporting that food.

Transporter's immediate previous source means a person from whom a transporter received food. This source can be either another transporter or a nontransporter.

Transporter's immediate subsequent recipient means a person to whom a transporter delivered food. This recipient can be either another transporter or a nontransporter.

You means a person subject to this subpart under § 1.326.

§ 1.329 Do other statutory provisions and regulations apply?

(a) In addition to the regulations in this subpart, you must comply with all other applicable statutory provisions and regulations related to the establishment and maintenance of records for foods except as described in paragraph (b) of this section. For example, the regulations in this subpart are in addition to existing recordkeeping regulations for low acid canned foods,

juice, seafood, infant formula, color additives, bottled water, animal feed, and medicated animal feed.

(b) Records established or maintained to satisfy the requirements of this subpart that meet the definition of electronic records in § 11.3(b)(6) (21 CFR 11.3 (b)(6)) of this chapter are exempt from the requirements of part 11 of this chapter. Records that satisfy the requirements of this subpart but that are also required under other applicable statutory provisions or regulations remain subject to part 11 of this chapter.

§ 1.330 Can existing records satisfy the requirements of this subpart?

The regulations in this subpart do not require duplication of existing records if those records contain all of the information required by this subpart. If a covered person keeps records of all of the information as required by this subpart to comply with other Federal, State, or local regulations, or for any other reason, then those records may be used to meet these requirements. Moreover, persons do not have to keep all of the information required by this rule in one set of records. If they have records containing some of the required information, they may keep those existing records and keep, either separately or in a combined form, any new information required by this rule. There is no obligation to create an entirely new record or compilation of records containing both existing and new information, even if the records containing some of the required information were not created at the time the food was received or released.

Requirements for Nontransporters to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Previous Sources of Food

§ 1.337 What information must nontransporters establish and maintain to identify the nontransporter and transporter immediate previous sources of food?

(a) If you are a nontransporter, you must establish and maintain the following records for all food you receive:

(1) The name of the firm, address, telephone number and, if available, the fax number and e-mail address of the nontransporter immediate previous source, whether domestic or foreign;

(2) An adequate description of the type of food received, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(3) The date you received the food;

(4) For persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent this information exists);

(5) The quantity and how the food is packaged (e.g., 6 count bunches, 25 pound (lb) carton, 12 ounce (oz) bottle, 100 gallon (gal) tank); and

(6) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter immediate previous source (the transporter who transported the food to you).

Requirements for Nontransporters to Establish and Maintain Records to Identify the Nontransporter and Transporter Immediate Subsequent Recipients of Food

§ 1.345 What information must nontransporters establish and maintain to identify the nontransporter and transporter immediate subsequent recipients of food?

(a) If you are a nontransporter, you must establish and maintain the following records for food you release:

(1) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the nontransporter immediate subsequent recipient, whether domestic or foreign;

(2) An adequate description of the type of food released, to include brand name and specific variety (e.g., brand x cheddar cheese, not just cheese; or romaine lettuce, not just lettuce);

(3) The date you released the food;

(4) For persons who manufacture, process, or pack food, the lot or code number or other identifier of the food (to the extent this information exists);

(5) The quantity and how the food is packaged (e.g., 6 count bunches, 25 lb carton, 12 oz bottle, 100 gal tank);

(6) The name of the firm, address, telephone number, and, if available, the fax number and e-mail address of the transporter immediate subsequent recipient (the transporter who transported the food from you); and

(b) Your records must include information reasonably available to you to identify the specific source of each ingredient used to make every lot of finished product.

Requirements for Transporters to Establish and Maintain Records

§ 1.352 What information must transporters establish and maintain?

If you are a transporter, you must establish and maintain the following records for each food you transport in the United States. You may fulfill this requirement by either:

(a) Establishing and maintaining the following records:

(1) Names of the transporter's immediate previous source and transporter's immediate subsequent recipient;

(2) Origin and destination points;

(3) Date shipment received and date released;

(4) Number of packages;

(5) Description of freight;

(6) Route of movement during the time you transported the food; and

(7) Transfer point(s) through which shipment moved; or

(b) Establishing and maintaining records containing the following information currently required by the Department of Transportation's Federal Motor Carrier Safety Administration (of roadway interstate transporters (49 CFR 373.101 and 373.103) as of [*insert date of publication in the* **Federal Register**]:

(1) Names of consignor and consignee;

(2) Origin and destination points;

(3) Date of shipment;

(4) Number of packages;

(5) Description of freight;

(6) Route of movement and name of each carrier participating in the transportation; and

(7) Transfer points through which shipment moved; or

(c) Establishing and maintaining records containing the following information currently required by the Department of Transportation's Surface Transportation Board of rail and water interstate transporters (49 CFR 1035.1 and 1035.2) as of [*insert date of publication in the* **Federal Register**:

(1) Date received;

(2) Received from;

(3) Consigned to;

(4) Destination;

(5) State of;

(6) County of;

(7) Route;

(8) Delivering carrier;

(9) Car initial;

(10) Car no;

(11) Trailer initials/number;

(12) Container initials/number;

(13) No. packages; and

(14) Description of articles; or

(d) Establishing and maintaining records containing the following information currently required by the Warsaw Convention of international air transporters on air waybills:

(1) Shipper's name and address;

(2) Consignee's name and address;

(3) Customs reference/status;

(4) Airport of departure and destination;

(5) First carrier; and

(6) Description of goods; or

(e) Entering into an agreement with the nontransporter immediate previous source located in the United States and/or the nontransporter immediate subsequent recipient located in the United States to establish, maintain, or establish and maintain, the information in § 1.352(a), (b), (c), or (d). The agreement must contain the following elements:

(1) Effective date;

(2) Printed names and signatures of authorized officials;

(3) Description of the records to be established and/or maintained;

(4) Provision for the records to be maintained in compliance with § 1.360, if the agreement provides for maintenance of records;

(5) Provision for the records to be available to FDA as required by § 1.361, if the agreement provides for maintenance of records;

(6) Acknowledgement that the nontransporter assumes legal responsibility under § 1.363 for establishing and/or maintaining the records as required by this subpart; and

(7) Provision that if the agreement is terminated in writing by either party, responsibility for compliance with the applicable establishment, maintenance, and access provisions of this subpart reverts to the transporter as of the date of termination.

§ 1.360 What are the record retention requirements?

(a) You must create the required records when you receive and release food, except to the extent that the information is contained in existing records.

(b) If you are a nontransporter, you must retain for 6 months after the dates you receive and release the food all required records for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date you receive or release the food.

(c) If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date you receive or release the food.

(d) If you are a nontransporter, you must retain for 2 years after the dates you receive and release the food all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than 6 months after the date you receive or release the food, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container.

(e) If you are a nontransporter, you must retain for 1 year after the dates you receive and release the food all required records for animal food, including pet food.

(f) If you are a transporter or nontransporter retaining records on behalf of a transporter, you must retain for 6 months after the dates you receive and release the food all required records for any food having a significant risk of spoilage, loss of value, or loss of palatability within 60 days after the date the transporter receives or releases the food. If you are a transporter, or nontransporter retaining records on behalf of a transporter, you must retain for 1 year after the dates you receive and release the food, all required records for any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days after the date the transporter receives or releases the food.

(g) You must retain all records at the establishment where the covered activities described in the records occurred (onsite) or at a reasonably accessible location.

(h) The maintenance of electronic records is acceptable. Electronic records are considered to be onsite if they are accessible from an onsite location.

§ 1.361 What are the record availability requirements?

When FDA has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, any records and other information accessible to FDA under section 414 or 704(a) of the act (21 U.S.C. 350c and 374(a)) must be made readily available for inspection and photocopying or other means of reproduction. Such records and other information must be made available as soon as possible, not to exceed 24 hours from the time of receipt of the official request, from an officer or employee duly designated by the Secretary of Health and Human Services who presents appropriate credentials and a written notice.

§ 1.362 What records are excluded from this subpart?

The establishment and maintenance of records as required by this subpart does not extend to recipes for food as defined in § 1.328; financial data, pricing data, personnel data, research data, or sales data (other than shipment data regarding sales).

§ 1.363 What are the consequences of failing to establish or maintain records or make them available to FDA as required by this subpart?

(a) The failure to establish or maintain records as required by section 414(b) of the act and this regulation or the refusal to permit access to or verification or copying of any such required record is a prohibited act under section 301 of the act.

(b) The failure of a nontransporter immediate previous source or a nontransporter immediate subsequent recipient who enters an agreement under § 1.352(c) to establish, maintain, or establish and maintain, records required under § 1.352(a) or (b), or the refusal to permit access to or verification or copying of any such required record, is a prohibited act under section 301 of the act.

(c) The failure of any person to make records or other information available to FDA as required by section 414 or 704(a) of the act and this regulation is a prohibited act under section 301 of the act.

Compliance Dates

§ 1.368 What are the compliance dates for this subpart?

The compliance date for the requirements in this subpart is [*insert date 12 months after date of publication in the* **Federal Register**]. However, the compliance dates for small and very small businesses are contained in paragraphs (a) and (b) of this section. The size of the business is determined using the total number of full-time equivalent employees in the entire business, not each individual location or establishment. A full-time employee counts as one full-time equivalent employee. Two part-time employees, each working half time, count as one full-time equivalent employee.

(a) The compliance date for the requirements in this subpart is [*insert date 18 months after date of publication in the* **Federal Register**], for small businesses employing fewer than 500, but more than 10 full-time equivalent employees.

(b) The compliance date for the requirements in this subpart is [*insert date 24 months after date of publication in the* **Federal Register**], for very small businesses that employ 10 or fewer full-time equivalent employees.

PART 11—ELECTRONIC RECORDS; ELECTRONIC SIGNATURES

■ 3. The authority citation for 21 CFR part 11 continues to read as follows:

Authority: 21 U.S.C. 321-393; 42 U.S.C. 262.

■ 4. Section 11.1 is amended by adding paragraph (f) to read as follows:

§ 11.1 Scope

* * * * *

(f) This part does not apply to records required to be established or maintained by §§ 1.326 through 1.368 of this chapter. Records that satisfy the requirements of part 1, subpart J of this chapter, but that also are required under other applicable statutory provisions or regulations, remain subject to this part.

NOV 30 2004

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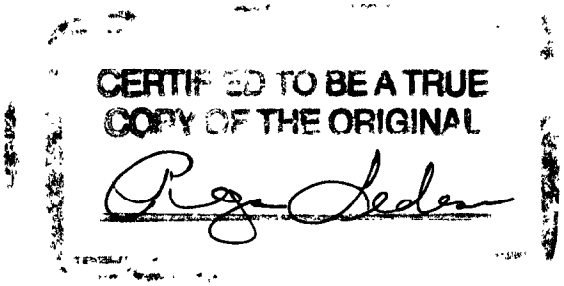
Dated: _____

November 30, 2004.

Lester M. Crawford,
Acting Commissioner of Food and Drugs.



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Dated: DEC - 2 2004

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Tommy D. Thompson

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