and ''Retail Food Safety References'' to list jurisdictions that have reported adoptions of the FDA Food Code. Because it is self-reported, the list is incomplete and has not been evaluated to determine whether all the adopted codes are equivalent to the model Food Code. It is important to FDA to have a comprehensive, accurate, and current inventory of Food Code adoptions to help achieve the aims of the President's Council on Food Safety and the agency's Food Safety Initiative goals.

FDA has obtained the services of AFDO to develop and implement an active surveillance system to track and report on the adoption of the FDA Food Code by State and local agencies and tribal nations of native Americans. The contractor will develop and maintain an active data base to track adoptions of the Food Code; identify and periodically contact State, local, and tribal food safety program administrators to determine the current status of adoptions of the Food Code or its equivalent; evaluate the equivalency of the adopted codes with the FDA Food Code; and provide quarterly progress reports to FDA from the data base in tabular and graphic form. Reports may be placed on the Internet at http://www.fda.gov.

Initial contacts by AFDO to local, State, and tribal program administrators will be by telephone and/or e-mail to determine the Food Code status in their jurisdiction(s). Verbal responses to questions will be acceptable as will electronic or facsimile information. Followup contacts to clarify responses will be by telephone or e-mail to minimize the burden on respondents.

The types of questions to be asked will be whether or not the FDA Food Code has been adopted in the respondent's jurisdiction, which version of the Food Code is in effect, and if not, which local jurisdictions need to be contacted for Food Code adoption status. AFDO will also determine with the local/State/tribal governments that it has the latest version of the code for analysis.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
500	2	1,000	1	1,000
Total Hours				1,000

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

FDA based its estimate on the number of State agencies (100) involved in Food Code-related regulatory programs, 300 local agencies with local ordinance authority that may consider Food Code adoption in any one year, and 100 tribal agencies. Estimating the number of local agencies is difficult before the start of this project because in some States, adoption by a State agency automatically applies to all local jurisdictions in that state. In other States, some metropolitan jurisdictions may adopt the FDA Food Code individually. Similar circumstances may apply to tribal nations' agencies that may be adopting the FDA Food Code. When the initial information gathering is completed, FDA will be able to identify more accurately the number of local and tribal agencies for which tracking adoption of the FDA Food Code will be necessary.

Frequency of reporting will range from once per year to quarterly for any one jurisdiction. This is because agencies that have already adopted the Food Code will require less frequent contact, perhaps only annually, than those that are in the process of adopting the Food Code. An average of two contacts in 1 year, therefore, was selected. Because most reporting will be done telephonically or electronically, reporting times often will be much less than 1 hour.

These estimates will fluctuate from year to year as agencies adopt, revise, and consider adoption of the FDA Food Code. Over the next 3 years, the frequency of contacts should decrease as jurisdictions adopt the FDA Food Code. This project will take several years to complete because the adoption process in some States can extend to 2 years or more. For example, some States have biennial legislative sessions. Others have extensive notice-and-comment administrative rulemaking procedures that can extend well beyond 1 year.

Dated: March 30, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–8416 Filed 4–5–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–4166]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Electronic Records; Electronic Signatures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by May 8, 2000.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Electronic Records; Electronic Signatures—Part 11 (21 CFR Part 11) (OMB Control Number 0910–0303)—Extension

FDA regulations in part 11 (21 CFR part 11) provide criteria for acceptance by FDA of electronic records, electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records and handwritten signatures executed on

paper. Under these regulations, records and reports may be submitted to FDA electronically, provided the agency has stated its ability to accept the records electronically in an agency-established public docket and that the other requirements of part 11 are met.

The recordkeeping provisions in part 11 (§§ 11.10, 11.30, 11.50, and 11.300) require standard operating procedures (SOP's) to ensure appropriate use of, and precautions for, systems using electronic records and signatures: (1) § 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) § 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; (3) § 11.50 specifies controls for signed electronic records; and (4) § 11.300 specifies controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords.

The burden created by the information collection provision of this regulation is a one-time burden associated with the creation of SOP's and validation. FDA anticipates the use of electronic media will substantially reduce the paperwork burden associated with maintaining FDA-required records.

The respondents will be businesses and other for-profit organizations, State or local governments, Federal agencies, and nonprofit institutions.

In the **Federal Register** of October 1, 1999 (64 FR 53392), in accordance with 5 CFR 1320.8(d), FDA announced an opportunity for public comment on the proposed collection of information on electronic records and electronic signatures. Comments from five respondents were received. In general, these comments addressed the costs of complying with the technical provisions of part 11 or used the opportunity as a forum to comment on the outcome of the final rule. Seven of these comments addressed the information collection and, in general, asserted that FDA had either underestimated the burden or had not considered all of the reporting and recordkeeping requirements. The comments on the information collection are addressed below.

(Comment 1) One comment submitted by industry stated that the creation of SOP's is not a one-time burden. It believes that the SOP's must be periodically reviewed and revised. FDA only requires the development of SOP's. FDA acknowledges that SOP's may need to be updated from time to time, but not necessarily because of an FDA requirement. If industry chooses to change their internal operations, then the associated change/update to the SOP's is a result of the company's choice to make changes, not a result of FDA requiring the change. Should SOP's need to be modified as a result of future changes to FDA regulations, FDA will consider the associated information collection burdens at the time it revises the relevant regulations.

(Comment 2) One comment asserted that the issuance of guidance documents further defines the expectations of FDA and, as such, requires industry to modify procedures and systems to reflect these new expectations. FDA recognizes that guidance documents may have additional reporting or recordkeeping requirements, however, the associated burden will be tied to the specific guidance document, and is not a part of this information collection. FDA will separately submit to OMB for review and clearance, any additional proposed collection of information associated with guidances.

(Comment 3) One comment stated that the regulation required industry to provide FDA with copies of software, as well as data. The comment added that this ''requirement'' places industry in the position of violating or renegotiating license agreements in order to comply with part 11. Part 11 does not require companies to provide FDA with copies of software.

(Comment 4) One comment asserted that FDA had ignored the burden in part 11 that requires industry to maintain records in electronic format for the full retention period. Electronic records must be retained for the same period applicable regulations require the equivalent paper records retained. The burden for retaining the records, in whatever form, is accounted for in the applicable FDA regulations.

(Comment 5) Two comments addressed the requirement for certification of electronic signatures. While reviewing these comments, FDA realized that under 5 CFR 1320.3(h)(1), ''affidavits, oaths, affirmations, certifications, receipts, changes of address, consents, or acknowledgments'' are not deemed to constitute a collection of information. Therefore, the reference to certification and the associated burden are being removed.

(Comment 6) One comment stated that its internal bureaucracy is such that it takes a long time to develop and approve a simple SOP, and therefore, FDA's estimate of cost was inaccurate. FDA has estimated the average annual burden. It will take some respondents more time and some less to develop and approve an SOP.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
11.10	2,250	1	2,250	20	45,000
11.30	2,250	1	2,250	20	45,000
11.50	4,500	1	4,500	20	90,000
11.300	4,500	1	4,500	20	90,000
Total					270,000

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

The burden created by this regulation is a one-time burden associated with the creation of SOP's and validation. The numbers reflect the combination of FDA's 3 years of experience in administering the program and an anticipated increase in the number of respondents. As the opportunity to submit and maintain documents electronically becomes more available to the public, the number of participants is expected to increase.

Dated: March 30, 2000.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 00–8415 Filed 4–5–00; 8:45 am]

BILLING CODE 4160–01–F