TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Part	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
113 and 114	7,915	1	7,915	250	1,978,750

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

The reporting burden for §§ 108.25(d) and 108.35(d) and (e) is insignificant because notification of spoilage, process deviation or contamination of product in distribution occurs less than once a year. Most firms discover these problems before the product is distributed and, therefore, are not required to report the occurrence. To avoid double-counting, estimates for §§ 108.25(g) and 108.35(h) have not been included because they merely cross reference recordkeeping requirements contained in parts 113 and 114.

Dated: January 28, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–2297 Filed 2–4–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0045]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Records; Electronic Signatures

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection provisions relating to FDA's electronic records and electronic signatures.

DATES: Submit written or electronic comments on the collection of information by April 8, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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

FDA regulations in part 11 (21 CFR part 11) provide criteria for acceptance of electronic records; electronic signatures, and handwritten signatures executed to electronic records as equivalent to paper records. Under these regulations, records and reports may be submitted to FDA electronically provided the agency has stated our 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 (SOPs) to assure appropriate use of, and precautions for, systems using electronic records and signatures: (1) Section 11.10 specifies procedures and controls for persons who use closed systems to create, modify, maintain, or transmit electronic records; (2) section 11.30 specifies procedures and controls for persons who use open systems to create, modify, maintain, or transmit electronic records; (3) section 11.50 specifies procedures and controls for persons who use electronic signatures; and (4) section 11.300 specifies controls to ensure the security and integrity of electronic signatures based upon use of identification codes in combination with passwords. The reporting provision (§ 11.100) requires persons to certify in writing to FDA that they will regard electronic signatures used in their systems as the legally binding equivalent of traditional handwritten signatures.

The burden created by the information collection provision of this regulation is a one-time burden associated with the creation of SOPs, validation, and certification. The agency 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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
11.100	4,500	1	4,500	1	4,500

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

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

Dated: February 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–2298 Filed 2–4–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N–0312]

Animal Feed Safety System: A Comprehensive Risk-Based Safety Program for the Manufacture and Distribution of Animal Feeds; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss our progress on development of a comprehensive, risk-based Animal Feed Safety System (AFSS) describing how animal feeds (individual ingredients and mixed feeds) should be manufactured, distributed, and used to minimize risks to humans and animals. We are seeking comments and assistance in our consideration of this safety program to effectively minimize the hazards to public health posed by animal feed products.

Date and Time: The public meting will be held on Tuesday, April 5, 2005, from 8 a.m. to 5 p.m., and Wednesday, April 6, 2005, from 8 a.m. to 12:15 p.m. You may submit written or electronic comments at any time, but they would be most helpful if received on or before March 4, 2005.

Location: The public meeting will be held at The Crowne Plaza, 655 North 108th Ave., Omaha, NE 68154, 402–496–0850.

ADDRESSES: You may submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments. You can view comments FDA has received on the Internet at *http://www.fda.gov/ohrms/dockets/*.

Contacts:

For General Information: Zoe Gill, Center for Veterinary Medicine (HFV–226), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6867, FAX: 240–453–6882, or e-mail: *zoe.gill@fda.gov*.

For Information About Registration: Brenda Boateng, Center for Veterinary Medicine (HFV–220), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6850, FAX: 240–453–6882, or e-mail: *brenda.boateng@fda.gov*.

Registration: Registration forms are available on the Division of Dockets Management Web site at *http://www.accessdata.fda.gov/scripts/oc/dockets/meetings/meetingdocket.cfm*. Although there is no registration fee for this meeting, registration is required. Due to limited meeting space, and to permit the agency to adequately prepare for the meeting, early registration is strongly encouraged. We are asking that registration occur by March 11, 2005. You may register by telephone, fax, or e-mail by contacting Brenda Boateng (*see Contacts*).

If you need special accommodations due to a disability, please contact Toni Wooten at 301–595–0796 or by e-mail at *toni.wooten@fda.gov* at least 7 days in advance of the meeting.

Transcripts: You may request a transcript of the meeting's general session in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857. The transcript will not include the individual breakout sessions, although their summaries will be included in the general session transcript. The transcript of the public meeting will be available after the meeting, at a cost of 10 cents per page. You may also examine the transcript of the meeting at the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday and on the CVM Web site at *http://www.fda.gov/cvm*.

SUPPLEMENTARY INFORMATION:

I. Background

We envision the AFSS as an umbrella regulatory program aimed at protecting human and animal health, It is intended to cover the labeling, production, and distribution of all feed ingredients and mixed feeds at all stages of manufacture, distribution, and use.

On September 23 and 24, 2003, we held a public meeting in Herndon, VA to discuss the AFSS. The public meeting included active participation of people