TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN—Continued

21 CFR Section	No. of Record-keepers	Annual Frequency per Recordkeepers	Total Annual Records	Hours per Record	Total Hours	Total Capital, Operating, and Maintenance Costs
101.13(q)(5)	265,000	1.5	397,500	0.75	298,125	0
101.14(d)(2)	265,000	1.5	397,500	0.75	298,125	0
101.22(i)(4)	25	1	25	1	25	0
101.100(d)(2)	1,000	1	1,000	1	1,000	0
101.105(t)	100	1	100	1	100	0
Total					597,400	0

These estimates are based on the document entitled ''Regulatory Impact Analysis of the Final Rules to Amend the Food Labeling Regulations,'' which is the agency's most recent comprehensive review of food labeling costs that published in the **Federal Register** of January 6, 1993 (58 FR 2927); agency communications with industry; and FDA's knowledge of and experience with food labeling and the submission of petitions and requests to the agency. Where an agency regulation implements an information collection requirement in the act or the FPLA, only any additional burden attributable to the regulation has been included in FDA's burden estimate.

No burden has been estimated for those requirements where the information to be disclosed is information that has been supplied by FDA. Also, no burden has been estimated for information that is disclosed to third parties as a usual and customary part of a food producer's normal business activities. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information. Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

Dated: January 12, 2001.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning, and Legislation.

[FR Doc. 01–1567 Filed 1–19–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1571]

Enrofloxacin for Poultry; Opportunity for Hearing; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Veterinary Medicine (CVM), is revising a notice of opportunity for hearing (NOOH) that published in the **Federal Register** on October 31, 2000 (65 FR 64954). After publishing the NOOH, CVM determined that some estimates of numbers of human campylobacteriosis cases and fluoroquinolone-resistant *Campylobacter* cases provided by a risk assessment used as a reference in the NOOH were incorrect. CVM has revised the risk assessment and is revising the estimates that were provided in the NOOH. This notice also extends the deadline for the sponsor to submit data and analysis upon which a request for a hearing relies. Other interested persons may submit comments on the NOOH before the deadline.

DATES: Submit all written data and analysis upon which a request for a hearing relies and other written comments by February 21, 2001.

ADDRESSES: Data and analysis and other comments are to be identified with Docket No. 00N–1571 and must be submitted to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

The revised risk assessment entitled ''The Human Health Impact of Fluoroquinolone Resistant *Campylobacter* Attributed to the Consumption of Chicken, Revised: January 5, 2001'' (hereafter referred to as Ref. 2a) is available electronically at http://www.fda.gov/cvm/antimicrobial/antimicrobial.html and in this docket.

FOR FURTHER INFORMATION CONTACT: Linda Tollefson, Center for Veterinary Medicine (HFV–200), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–2950.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 31, 2000 (65 FR 64954), CVM published an NOOH proposing withdrawal of the approval of a new animal drug application (NADA) for the use of the fluoroquinolone enrofloxacin in poultry. The NOOH included estimates that were taken from Ref. 2 of the October 31, 2000, NOOH, the risk assessment entitled ''Human Health Impact of Fluoroquinolone Resistant *Campylobacter* Attributed to the Consumption of Chicken, October 18, 2000.'' After publication of the NOOH, CVM determined that two of the cell references in the risk assessment were mislabeled and as a result, the model outputs were incorrect. CVM has revised the risk assessment to correct the cell references. Because CVM needed to make these corrections to the risk assessment, it has also incorporated the final FoodNet data for 1999 into the risk assessment and has made other related changes. CVM is revising the NOOH to reflect the changes in the risk assessment and to add the revised risk assessment Ref. 2a to the list of references in the NOOH. CVM does not believe that these revisions in any way alter the underlying basis of the NOOH.

The following section describes the location and revisions to the October 31, 2000, NOOH.

II. Revisions

Based on the revisions to the risk assessment, CVM is revising the estimates in the October 31, 2000, NOOH for the mean estimate of cases of campylobacteriosis; the mean estimate of the domestically-acquired

fluoroquinolone-resistant *Campylobacter* cases in humans attributable to consumption of chicken; and the mean estimate of the number of people who were infected with fluoroquinolone-resistant *Campylobacter* from consuming or handling chicken and who subsequently received a fluoroquinolone as therapy for their illness. CVM is also adding the revised risk assessment to the References section of the NOOH.

Table 1 provides the location and actual revisions of items in the NOOH.

TABLE 1.—REVISIONS TO THE OCTOBER 31, 2000, NOOH

Location	Sentence as published	Correction
64955, 2d column, beginning on the 9th line from bottom of page	The risk assessment determined * * * a mean estimate of 11,477 persons (5th and 95th percentiles: 6,412 and 18,978) * * *''	''The risk assessment determined * * * a mean estimate of 9,261 persons, (5th and 95th percentiles: 5,227 and 15,326) * * *''
64962, 1st column, beginning on the 8th line	''Using the data on human *Campylobacter* * * * calculated a mean estimate of 1.7 million cases of campylobacteriosis (5th and 95th percentiles: 1.1 million and 2.7 million) for 1999 (Ref. 2).''	''Using the data on human*Campylobacter* * * * calculated a mean estimate of 1.4 million cases of campylobacteriosis (5th and 95th percentiles: 0.9 million and 2.1 million) for 1999 (Ref. 2a).''
64962, 1st column, 1st full paragraph, beginning on the 7th line from the bottom of the paragraph	''For 1999, the mean estimate of * * * is 190,421 (5th and 95th percentiles: 103,471 and 318,321) (Ref. 2).''	''For 1999, the mean estimate of * * * is 153,580 (5th and 95th percentiles: 83,990 and 258,047) (Ref. 2a).''
64962, 1st column, 2d full paragraph, beginning on the 7th line	''For 1999, the estimated * * * 11,477 (5th and 95th percentiles: 6,412 and 18,978) (Ref. 2).''	''For 1999, the estimated * * * a mean estimate of 9,261 persons, (5th and 95th percentiles: 5,227 and 15,326) (Ref. 2a).''
64962, 2d column, 1st full paragraph, beginning on the 13th line from the bottom of the paragraph	''The risk assessment determined in 1999 a mean estimate of 11, 477 people (5th and 95th percentiles: 6,412 and 18,978) * * *''	''The risk assessment determined in 1999 a mean estimate of 9,261 people (5th and 95th percentiles: 5,227 and 15,326) * * *''
64963, 2d column under IX. References, between Refs. 2 and 3		Insert the following reference between Refs. 2 and 3: ''2a. The Human Health Impact of Fluoroquinolone Resistant*Campylobacter* Attributed to the Consumption of Chicken, Revised: January 5, 2001.''

Dated: January 16, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01–1866 Filed 1–18–01; 11:03 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1685]

New Food Chemicals Codex Monographs, Revisions of Certain Food Chemicals Codex Monographs, a New General Test Procedure, and Revisions to a Policy; Opportunity for Public Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on proposed new Food Chemicals Codex specification monographs, proposed changes to certain Food Chemicals Codex specification monographs, a proposed new general test procedure, and proposed changes to a policy in the fourth edition. Additions, revisions, and corrections to current specification monographs for certain substances used as food ingredients and to a policy, as well as new monographs and a new general test procedure, are being prepared by The National Academies, Institute of Medicine (IOM), Committee on Food Chemicals Codex (the committee). This material is expected to be included in the next publication of the Food Chemicals Codex (the third supplement to the fourth edition), scheduled for public release in the summer of 2001.

DATES: Submit written comments by March 8, 2001. (The committee advises that comments received after this date may not be considered for the third supplement to the fourth edition. Comments received too late for consideration for the third supplement will be considered for later supplements or for a new edition of the Food Chemicals Codex.)

ADDRESSES: Submit written comments and supporting data and documentation to the Committee on Food Chemicals Codex/FO–3042, Food and Nutrition Board, Institute of Medicine, 2101 Constitution Ave. NW., Washington, DC 20418. Copies of the proposed new Food Chemicals Codex specification monographs, proposed changes to certain monographs, the proposed new general test procedure, and the proposed changes to a policy may be obtained upon written request from the IOM (address above) or may be examined at the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests for copies should specify by name the monographs, general test procedure, or policy desired. For electronic access see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Ricardo Molins, Project Director/FO–3042, Committee on Food Chemicals Codex, Food and Nutrition Board, Institute of Medicine, 2101 Constitution Ave. NW., Washington, DC 20418, 202–334–2580; or

Paul M. Kuznesof, Division of Product Manufacture and Use (HFS–246), Office of Premarket Approval, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3009.

SUPPLEMENTARY INFORMATION: By contract with the IOM, FDA supports the preparation of the Food Chemicals Codex, a compendium of specification monographs for substances used as food ingredients. Before any specifications are included in a Food Chemicals Codex publication, public announcement is made in the **Federal Register**. All interested parties are invited to comment and to make suggestions for consideration. Suggestions should be accompanied by supporting data or other documentation to facilitate and expedite review by the committee.