American Academy of Pediatrics, physicians can play an important role in educating parents about ways to promote their child's sexual health. The total annual burden for this project is 300 hours.

Respondents	Number of respondents	Number of responses	Average hour burden per response
Pediatricians	900	1	20/60

Dated: January 16, 2001.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 01–1763 Filed 1–19–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1283]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Food Labeling Regulations

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 (the PRA).

DATES: Submit written comments on the collection of information by February 21, 2001.

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: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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.

Food Labeling Regulations—21 CFR Parts 101, 102, 104, and 105 (OMB Control No. 0910–0381)—Extension

FDA regulations require food producers to disclose to consumers and others specific information about themselves or their products on the label or labeling of their products. Related regulations require that food producers retain records establishing the basis for the information contained in the label or labeling of their products and provide those records to regulatory officials. Finally, certain regulations provide for the submission of food labeling petitions to FDA. FDA's food labeling regulations in parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105) were issued under the authority of sections 4, 5, and 6 of the Fair Packaging and Labeling Act (the FPLA) (15 U.S.C. 1453, 1454, and 1455) and of sections 201, 301, 402, 403, 409, 411, 701, and 721 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321, 331, 342, 343, 348, 350, 371, and 379e). Most of these regulations derive from section 403 of the act, which provides that a food product shall be deemed to be misbranded if, among other things, its label or labeling fails to bear certain required information concerning the food product, is false or misleading in any particular, or bears certain types of unauthorized claims. The disclosure requirements and other collections of information in the regulations in parts 101, 102, 104, and 105 are necessary to ensure that food products produced or sold in the United States are in compliance with the labeling provisions of the act and the FPLA.

Section 101.3 of FDA's food labeling regulations requires that the label of a food product in packaged form bear a statement of identity (i.e., the name of the product), including, as appropriate, the form of the food or the name of the food imitated. Section 101.4 prescribes requirements for the declaration of ingredients on the label or labeling of food products in packaged form. Section 101.5 requires that the label of a food product in packaged form specify the name and place of business of the manufacturer, packer, or distributor and, if the food producer is not the manufacturer of the food product, its connection with the food product. Section 101.9 requires that nutrition information be provided for all food products intended for human consumption and offered for sale, unless an exemption in § 101.9(j) applies to the product. Section 101.9(g)(9) also provides for the submission to FDA of requests for alternative approaches to nutrition labeling. Finally, § 101.9(j)(18) provides for the submission to FDA of notices from firms claiming the small business exemption from nutrition labeling.

Section 101.10 requires that restaurants provide nutrition information, upon request, for any food or meal for which a nutrient content claim or health claim is made. Section 101.12(b) provides the reference amount that is used for determining the serving sizes for baking powder, baking soda, and pectin. Section 101.12(e) provides that a manufacturer that adjusts the reference amount customarily consumed (RACC) of an aerated food for the difference in density of the aerated food relative to the density of the appropriate nonaerated reference food must be prepared to show FDA detailed protocols and records of all data that were used to determine the density-adjusted RACC. Section 101.12(g) requires that the label or labeling of a food product disclose the serving size that is the basis for a claim made for the product if the serving size on which the claim is based differs from the RACC. Section 101.12(h) provides for the submission of petitions to FDA to request changes in the reference amounts defined by regulation.

Section 101.13 requires that nutrition information be provided in accordance with § 101.9 for any food product for which a nutrient content claim is made. Under some circumstances, § 101.13 also requires the disclosure of other types of information as a condition for the use of a nutrient content claim. For example, under § 101.13(j), if the claim compares the level of a nutrient in the food with the level of the same nutrient in another ''reference'' food, the claim must also disclose the identity of the reference food, the amount of the nutrient in each food, and the

percentage or fractional amount by which the amount of the nutrient in the labeled food differs from the amount of the nutrient in the reference food. It also requires that when this comparison is based on an average of served foods, this information must be provided to consumers or regulatory officials upon request. Section 101.13(q)(5) requires that restaurants document and provide to appropriate regulatory officials, upon request, the basis for any nutrient content claims they have made for the foods they sell.

Section 101.14 provides for the disclosure of nutrition information in accordance with § 101.9 and, under some circumstances, certain other information as a condition for making a health claim for a food product. Section 101.15 provides that, if the label of a food product contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in both the foreign language and in English. Section 101.22 contains labeling requirements for the disclosure of spices, flavorings, colorings, and chemical preservatives in food products. Section 101.22(i)(4) sets forth reporting and recordkeeping requirements pertaining to certifications for flavors designated as containing no artificial flavor. Section 101.30 specifies the conditions under which a beverage that purports to contain any fruit or vegetable juice must declare the percentage of juice present in the beverage and the manner in which the declaration is to be made.

Section 101.36 requires that nutrition information be provided for dietary supplements offered for sale, unless an exemption in § 101.36(h) applies. Section 101.36(f)(2) cross-references the provisions in § 101.9(g)(9) for the submission to FDA of requests for alternative approaches to nutrition labeling. Also, § 101.36(h)(2) cross-references the provisions in § 101.9(j)(18) for the submission of small business exemption notices.

Section 101.42 requests that food retailers voluntarily provide nutrition information for raw fruits, vegetables, and fish at the point of purchase, and § 101.45 contains guidelines for providing such information. Also, § 101.45(c) provides for the submission of nutrient data bases and proposed nutrition labeling values for raw fruit, vegetables, and fish to FDA for review and approval.

Sections 101.54, 101.56, 101.60, 101.61, and 101.62 specify information that must be disclosed as a condition for making particular nutrient content claims. Section 101.67 cross-references requirements in other regulations for ingredient declaration (§ 101.4) and disclosure of information concerning performance characteristics (§ 101.13(d)). Section 101.69 provides for the submission of a petition requesting that FDA authorize a particular nutrient content claim by regulation. Section 101.70 provides for the submission of a petition requesting that FDA authorize a particular health claim by regulation. Section 101.77(c)(2)(ii)(D) requires the disclosure of the amount of soluble fiber per serving in the nutrition labeling of a food bearing a health claim about the relationship between soluble fiber and a reduced risk of coronary heart disease. Section 101.79(c)(2)(iv) requires the disclosure of the amount of folate per serving in the nutrition labeling of a food bearing a health claim about the relationship between folate and a reduced risk of neural tube defects.

Section 101.100(d) provides that any agreement that forms the basis for an exemption from the labeling requirements of section 403(c), (e), (g), (h), (i), (k), and (q) of the act be in writing and that a copy of the agreement be made available to FDA upon request. Section 101.100 also contains reporting and disclosure requirements as conditions for claiming certain labeling exemptions.

Section 101.105 specifies requirements for the declaration of the net quantity of contents on the label of a food in packaged form and prescribes conditions under which a food whose label does not accurately reflect the actual quantity of contents may be sold, with appropriate disclosures, to an institution operated by Federal, State, or local government. Section 101.108 provides for the submission to FDA of a written proposal requesting a temporary exemption from certain requirements of §§ 101.9 and 105.66 for the purpose of conducting food labeling experiments with FDA's authorization.

Regulations in part 102 define the information that must be included as part of the statement of identity for particular foods and prescribe related labeling requirements for some of these foods. For example, § 102.22 requires that the name of a protein hydrolysate shall include the identity of the food source from which the protein was derived.

Part 104, which pertains to nutritional quality guidelines for foods, cross-references several labeling provisions in part 101 but contains no separate information collection requirements.

Part 105 contains special labeling requirements for hypoallergenic foods, infant foods, and certain foods represented as useful in reducing or maintaining body weight.

The disclosure and other information collection requirements in the above regulations are placed primarily upon manufacturers, packers, and distributors of food products. Because of the existence of exemptions and exceptions, not all of the requirements apply to all food producers or to all of their products. Some of the regulations affect food retailers, such as supermarkets and restaurants.

The purpose of the food labeling requirements is to allow consumers to be knowledgeable about the foods they purchase. Nutrition labeling provides information for use by consumers in selecting a nutritious diet. Other information enables a consumer to comparison shop. Ingredient information also enables consumers to avoid substances to which they may be sensitive. Petitions or other requests submitted to FDA provide the basis for the agency to permit new labeling statements or to grant exemptions from certain labeling requirements. Recordkeeping requirements enable FDA to monitor the basis upon which certain label statements are made for food products and whether those statements are in compliance with the requirements of the act or the FPLA.

In the **Federal Register** of October 10, 2000 (65 FR 60195), the agency requested comments on the proposed collection of information. The agency received several comments, none of which were relevant to the PRA.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Sections and Parts	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours Per Response	Total Hours	Total Capital, Operating, and Maintenance Costs
101.3 and 101.22, and 102 and 104	17,000	1.03	17,500	0.5	8,750	0
101.4, 101.22, and 101.100, and 102, 104, and 105	17,000	1.03	17,500	1	17,500	0
101.5	17,000	1.03	17,500	0.25	4,375	0
101.9, 101.13(n), 101.14(d)(3), and 101.62, and 104	17,000	1.03	17,500	4	70,000	$1,000,000
101.9(g)(9) and 101.36(f)(2)	12	1	12	4	48	0
101.9(j)(18) and 101.36(h)(2)	10,000	1	10,000	8	80,000	0
101.10	265,000	1.5	397,500	0.25	99,375	0
101.12(b)	29	2.3	66	1	66	$39,600
101.12(e)	25	1	25	1	25	0
101.12(g)	5,000	1	5,000	1	5,000	0
101.12(h)	5	1	5	80	400	$400,000
101.13(d)(1) and 101.67	200	1	200	1	200	0
101.13(j)(2), 101.13(k), 101.54, 101.56, 101.60, 101.61, and 101.62	2,500	1	2,500	1	2,500	0
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
101.15	160	10	1,600	8	12,800	0
101.22(i)(4)	25	1	25	1	25	0
101.30 and 102.33	1,500	3.3	5,000	1	5,000	0
101.36	300	40	12,000	4	48,000	$15,000,000
101.42 and 101.45	72,270	1	72,270	0.50	36,135	0
101.45(c)	5	4	20	4	80	0
101.69	3	1	3	25	75	0
101.70	3	1	3	80	240	$400,000
101.77(c)(2)(ii)(D)	1,000	1	1,000	0.25	250	0
101.79(c)(2)(iv)	100	1	100	0.25	25	0
101.100[2]	1,000	1	1,000	1	1,000	0
101.105 and 101.100(h)	17,000	1.03	17,500	0.5	8,750	0
101.108	0	0	0	40	0	0
Total					996,869[1]	$16,800,000

[1]Due to a clerical error, the total that appeared in table 1 in the **Federal Register** of Tuesday, October 10, 2000 (65 FR 60195), was incorrect. Table 1 of this document contains the correct estimates.

[2]Sections 101.14(d)(2) and 101.100(d) were incorrectly cited in table 1 in the **Federal Register** of Tuesday, October 10, 2000 (65 FR 60195). Table 1 of this document contains the correct citations.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeepers	Total Annual Records	Hours per Record	Total Hours	Total Capital, Operating, and Maintenance Costs
101.12(e)	25	1	25	1	25	0

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