National Heart, Lung, and Blood Institute (NHLBI), NIH, and currently at the Institute of Infectious Diseases, Southwest Hospital, Third Military Medical University, Chonqing, China, engaged in research misconduct in research supported by intramural research at NHLBI, NIH.

The questioned research involves a Western blot analysis of IgM and IgG antibodies from Chinese subjects in patients with non-A–E hepatitis and control subjects to test reactivity towards a newly discovered virus. Analysis of Figure 6 of the published paper and Figure S4 of the online supplemental information identified thirteen pairs of Western blot bands which had a common origin yet were labeled as from different subjects and usually as detecting a different class of immunoglobulin. Specifically the following pairs were shown to match using forensically useful tools in Photoshop. Each represent a falsification in one or both of the figures as indicated in the table:

Identity of strips	Located in:
A1 IgM/F1 IgG	Fig. 6 & Fig. S4.
B6 IgM/E1 IgM	Fig. 6 & Fig. S4.
D7 IgM/A11 IgG	Fig. 6 & Fig. S4.
G3 IgM/H4 IgG	Fig. S4.
H9 IgM/F4 IgG	Fig. S4.
A4 IgM/E2 IgG	Fig. S4.
A5 IgM/B9 IgM	Fig. S4.
C9 IgG/C6 IgM	Fig. S4.
D11 IgM/H11 IgG	Fig. S4.
D5 IgM/A1 IgG	Fig. S4.
A10 1gM/F7 IgG	Fig. S4.
C11 1gM/E9 IgG	Fig. 6.
F3 IgG/E9 IgM	F3 in S4/E9 in Fig. 6.

The Respondent agreed to correction of Figures 6 and S4 of the *PNAS* paper.

Dr. Xu has entered into a Voluntary Settlement Agreement and has voluntarily agreed for a period of three (3) years, beginning on December 6, 2013:

(1) That prior to the submission of an application for U.S. Public Health Service (PHS) support (including NIH support) for a research project on which the Respondent's participation is proposed, and prior to Respondent's participation in any capacity on PHS-supported research, Respondent shall ensure that a plan for supervision of her duties is submitted to ORI for approval; the supervision plan must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agrees that she shall not participate in any PHS-supported research until such a supervision plan is submitted to and approved by ORI; Respondent agrees to maintain responsibility for compliance with the agreed-upon supervision plan;

(2) That any institution employing her shall submit, in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS-supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived, that the data procedures, and methodology are accurately reported in the application, report, manuscript, or abstract, and that the text in such submission is her own or properly cites the source of copied language and ideas; and

(3) To exclude herself voluntarily from serving in any advisory capacity to PHS including, but not limited to, service on any PHS advisory committee, board, and/or peer review committee, or as a consultant.

FOR FURTHER INFORMATION CONTACT: Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8800.

David E. Wright,

Director, Office of Research Integrity.

[FR Doc. 2013–31160 Filed 12–27–13; 8:45 am]

BILLING CODE 4150–31–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1155]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Labeling Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Fax written comments on the collection of information by January 29, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0381. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

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 Number 0910–0381)—Revision to Include Collections Previously Approved By OMB, But Currently in Use Without Approval

Our food labeling 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 us. We issued our food labeling regulations under parts 101, 102, 104, and 105 (21 CFR parts 101, 102, 104, and 105) under the authority of sections 4, 5, and 6 of the Fair Packaging and Labeling Act (FPLA) (15 U.S.C. 1453, 1454, and 1455) and sections 201, 301, 402, 403, 409, 411, 701, and 721 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 321, 331, 342, 343, 348, 350, 371, and 379e). Most of these regulations derive from section 403 of the FD&C 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 FD&C Act and FPLA.

Upon review of the information collection requests supporting these food labeling regulations, FDA found that the third-party disclosure burdens associated with the requirements found in §§ 101.9(c)(2)(ii) and 101.36(b)(2) to

declare the amount of *trans* fatty acids present in a food, and with the voluntary declaration of the quantitative amount and the percent of Daily Value of a dietary ingredient on a ''per day'' basis in addition to the required ''per serving'' basis are in use without current OMB approval. These collections of information were previously approved by OMB under control numbers 0910–0595 and 0910–0395 respectively; however, the approval period for these collections has expired. To remedy this oversight, to most appropriately streamline these information collections, and to eliminate redundancy in its information collection requests, we seek to revise the instant collection to include these third-party disclosure elements and have included them in the burden estimates and discussion in this document in support of our approval request for OMB control number 0910–0381.

Section 101.3 of our 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. In particular, § 101.9(c)(2)(ii) requires that the amount of *trans* fatty acids present in a food must be declared on the nutrition label on a separate line immediately under the line for the declaration of saturated fat. Section 101.9(g)(9) provides that interested parties may submit to us requests for alternative approaches to nutrition labeling requirements. Finally, § 101.9(j)(18) provides that firms claiming the small business exemption from nutrition labeling must submit notice to us supporting their claim exemption. We developed Form FDA 3570 to assist small businesses in claiming the small business exemption from nutrition labeling. The form contains all the elements required by § 101.9(j)(18).

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 specific products, including 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 non-aerated reference food must be prepared to show us 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 requesting that we change 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 food products, 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(d)(2) and (d)(3) 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 FD&C Act to appear on the label must appear 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 disclosure and recordkeeping requirements pertaining to certifications for flavors designated as containing no artificial flavors. 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. In particular, § 101.36(b)(2) requires that the amount of *trans* fatty acids present in dietary supplements must be declared on the nutrition label on a separate line immediately under the line for the declaration of saturated fat. Section 101.36(e) permits the voluntary declaration of the quantitative amount and the percent of Daily Value of a dietary ingredient on a ''per day'' basis in addition to the required ''per serving'' basis, if a dietary supplement label recommends that the dietary supplement be consumed more than once per day. Section 101.36(f)(2) cross-references the provisions in § 101.9(g)(9) for the submission to us of requests for alternative approaches to nutrition labeling requirements. Also, § 101.36(h)(2) cross-references the provisions in § 101.9(j)(18) for the submission of small business exemption notices. As noted previously, we developed Form FDA 3570 to assist small businesses in claiming the small business exemption from nutrition labeling. The form contains all the elements required by § 101.36(h)(2).

Section 101.42 requests that food retailers voluntarily provide nutrition information for raw fruit, 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 to us of nutrient databases and proposed nutrition labeling values for raw fruit, vegetables, and fish 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 provides for the use of nutrient content claims for butter, and cross-references requirements in other regulations for information 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 we authorize a particular nutrient content claim by regulation. Section 101.70 provides for the submission of a petition requesting that we authorize a particular health claim by regulation. Section 101.77(c)(2)(ii)(D) requires the disclosure 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 in the nutrition label 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 FD&C Act be in writing and that a copy of the agreement be made available to us upon request. Section 101.100 also contains reporting and disclosure requirements as conditions for claiming certain labeling exemptions (e.g., 101.100(h)).

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 a Federal, State or local government. Section 101.108 provides for the submission to us 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 our 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 will 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 purpose of our 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 us provide the basis for us to permit new labeling statements or to grant exemptions from certain labeling requirements. Recordkeeping requirements enable us 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 FD&C Act or FPLA.

Description of Respondents: Respondents to this information collection are 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.

In the **Federal Register** of November 1, 2013 (78 FR 65663), FDA published a 60-day notice requesting public comment on the proposed collection of information. Several comments were received in response to the notice. Many were generally supportive of the necessity of our food labeling regulations. Other comments were beyond the scope of the four collections of information topics on which the notice solicits comments and will therefore not be discussed in this document.

A number of comments referenced our **Federal Register** notice published on November 8, 2013 (78 FR 67169) (''the November 8, 2013, notice''), announcing the tentative determination that partially hydrogenated oils (PHOs) are no longer ''generally recognized as safe'' (GRAS). Some comments supported this determination while others opposed it. Supportive comments suggested that labels should be placed on food packaging warning consumers of the negative health effects of the *trans* fatty acid component of PHOs. FDA notes that it does not require warning labels on food containing *trans* fatty acid, but we agree that *trans* fatty acid content should be provided in the nutrition labeling of food. In the **Federal Register** of July 11, 2003 (68 FR 41434), we issued a final rule (''the July 2003 final rule'') amending our nutrition labeling regulations to require declaration of the *trans* fatty acid content of food in the nutrition label of conventional foods and dietary supplements (§ 101.9(c)(2)(ii)). This requirement was effective January 1, 2006. The November 8, 2013, notice seeks comments on our preliminary determination that PHOs are not GRAS and we have submitted comments relevant to this topic to that docket as well. If FDA makes a final determination that PHOs are not GRAS, the food industry would be required to phase out the use of PHOs in food over time, not place warning labels on their food products.

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

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
101.3, 101.22, 102, and 104; statement of identity labeling requirements	25,000	1.03	25,750	0.5	12,875
101.4, 101.22, 101.100, 102, 104, and 105; ingredient labeling requirements	25,000	1.03	25,750	1	25,750
101.5; requirement to 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	25,000	1.03	25,750	0.25	6,438
101.9, 101.13(n), 101.14(d)(3), 101.62, and 104; labeling requirements for disclosure of nutrition information	25,000	1.03	25,750	4	103,000
101.9(g)(9) and 101.36(f)(2); alternative means of compliance permitted	12	1	12	4	48

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
101.10; requirements for nutrition labeling of restaurant foods	300,000	1.5	450,000	0.25	112,500
101.12(b); RACC for baking powder, baking soda, and pectin	29	2.3	67	1	67
101.12(e); adjustment to the RACC of an aerated food permitted	25	1	25	1	25
101.12(g); requirement to 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	5,000	1	5,000	1	5,000
101.13(d)(1) and 101.67; requirements to disclose nutrition information for any food product for which a nutrient content claim is made	200	1	200	1	200
101.13(j)(2), 101.13(k), 101.54, 101.56, 101.60, 101.61, and 101.62; additional disclosure required if the nutrient content claim compares the level of a nutrient in one food with the level of the same nutrient in another food	5,000	1	5,000	1	5,000
101.13(q)(5); requirement that restaurants disclose the basis for nutrient content claims made for their food	300,000	1.5	450,000	0.75	337,500
101.14(d)(2); general requirements for disclosure of nutrition information related to health claims for food products	300,000	1.5	450,000	0.75	337,500
101.15; requirements pertaining to prominence of required statements and use of foreign language	160	10	1,600	8	12,800
101.22(i)(4); supplier certifications for flavors designated as containing no artificial flavors	25	1	25	1	25
101.30 and 102.33; labeling requirements for fruit or vegetable juice beverages	1,500	5	7,500	1	7,500
101.36; nutrition labeling of dietary supplements	300	40	12,000	4.025	48,300
101.42 and 101.45; nutrition labeling of raw fruits, vegetables, and fish	1,000	1	1,000	0.5	500
101.45(c); databases of nutrient values for raw fruits, vegetables, and fish	5	4	20	4	80
101.79(c)(2)(i)(D); disclosure requirements for food labels that contain a folate/neural tube defect health claim	1,000	1	1,000	0.25	250
101.79(c)(2)(iv); disclosure of amount of folate for food labels that contain a folate/neural tube defect health claim	100	1	100	0.25	25
101.100(d); disclosure of agreements that form the basis for exemption from the labeling requirements of section 403(c), (e), (g), (h), (i), (k), and (q) of the FD&C Act	1,000	1	1,000	1	1,000
101.105 and 101.100(h); disclosure requirements for food not accurately labeled for quantity of contents and for claiming certain labeling exemptions	25,000	1.03	25,750	0.5	12,875
Total					1,029,258

[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	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
101.12(e); recordkeeping to document the basis for density-adjusted RACC	25	1	25	1	25
101.13(q)(5); recordkeeping to document the basis for nutrient content claims	300,000	1.5	450,000	0.75	337,500
101.14(d)(2); recordkeeping to document nutrition information related to health claims for food products	300,000	1.5	450,000	0.75	337,500
101.22(i)(4); recordkeeping to document supplier certifications for flavors designated as containing no artificial flavors	25	1	25	1	25
101.100(d)(2); recordkeeping pertaining to agreements that form the basis for an exemption from the labeling requirements of section 403(c), (e), (g), (h), (i), (k), and (q) of the FD&C Act	1,000	1	1,000	1	1,000

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
101.105(t); recordkeeping pertaining to disclosure requirements for food not accurately labeled for quantity of contents	100	1	100	1	100
Total					676,150

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

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section/Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
101.9(j)(18) and 101.36(h)(2); procedure for small business nutrition labeling exemption notice using Form FDA 3570	10,000	1	10,000	8	80,000
101.12(h); petitions to establish or amend a RACC	5	1	5	80	400
101.69; petitions for nutrient content claims	3	1	3	25	75
101.70; petitions for health claims	5	1	5	80	400
101.108; written proposal for requesting temporary exemptions from certain regulations for the purpose of conducting food labeling experiments	1	1	1	40	40
Total					80,915

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

The estimated annual third-party disclosure, recordkeeping, and reporting burdens are based on our communications with industry and our knowledge of and experience with food labeling and the submission of petitions and requests to us.

As noted, we are revising this collection to include previously approved third-party disclosure burdens associated with the requirement to declare the amount of *trans* fatty acids present in a food, including dietary supplements. The third-party disclosure burden hours formerly associated with OMB control number 0910–0515 (collection entitled, ''Food Labeling: Trans Fatty Acids in Nutrition Labeling'') are represented by the citation to § 101.9 on line 4 of table 1 and the citation to § 101.36 on line 17 of table 1. For this revision, we have not added burden hours to line 4 or line 17 of table 1 because, based on our experience with food labeling, the 4 hours estimated for meeting the labeling requirements of § 101.9 and the 4 hours estimated for meeting the labeling requirements of § 101.36 are appropriate estimates of the total time it takes a respondent to meet our requirements for nutrition labeling in §§ 101.9 and 101.36.

We are also revising this collection to include previously approved third-party disclosure burdens associated with the voluntary declaration of the quantitative amount and the percent of Daily Value of a dietary ingredient on a ''per day'' basis in addition to the required ''per serving'' basis. The third-party disclosure burden hours formerly associated with OMB control number 0910–0395 (collection entitled, ''Food Labeling: Nutrition Labeling of Dietary Supplements on a 'Per Day' Basis'') are represented by the citation to § 101.36 on line 17 of Table 1 and the addition of 300 hours to our previous estimate of 48,000 hours. For this revision, we added 300 burden hours to line 17 of table 1 because voluntary labeling on a ''per day'' basis is in addition to the required ''per serving'' basis. We estimate that ''per day'' information would generally be placed on, at most, 10 percent of the estimated 12,000 disclosures, for a total of 1,200 annual disclosures, and that a respondent will spend 15 minutes (0.25 hours) per disclosure, for a total of 300 hours. Thus, the total estimated burden on line 17 of table 1 is 48,300 hours and average burden per disclosure on line 17 of table 1 has been increased from 4.0 to 4.025 hours, to represent an averaging of the burden hours across all of the estimated 12,000 disclosures.

We expect that the burden hours for submissions under § 101.108 will be insignificant. Section 101.108 was originally issued to provide a procedure whereby we could grant exemptions from certain food labeling requirements. Exemption petitions have infrequently been submitted in the recent past; none have been submitted since publication on January 6, 1993, of the final regulations implementing section 403(q) and (r) of the FD&C Act. Thus, in order to maintain OMB approval of § 101.108 to accommodate the possibility that a food producer may propose to conduct a labeling experiment on its own initiative, we estimate that we will receive one or fewer submissions under § 101.108 in the next 3 years.

Dated: December 23, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–31215 Filed 12–27–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1676]

International Drug Scheduling; Convention on Psychotropic Substances; Single Convention on Narcotic Drugs; Tapentadol; Tramadol; Ketamine; gamma-Butyrolactone; 22 Additional Substances; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting