(b) Disclosure Labor Cost

The estimated annual labor cost for disclosures for all telemarketing entities is $17,923,044. This total is the product of applying an assumed hourly wage rate of $14.74 [44] to the earlier stated estimate of 1,215,946 hours pertaining to the pre-sale, general and specific disclosures.

(c) Reporting Labor Cost

Estimated labor cost supplying basic identifying information to the Registry operator is $3,228 (219 hours × $14.74 per hour).

Thus, cumulatively for both new and existing telemarketing entities total labor costs are $18,367,441 [($441,169 recordkeeping) + ($17,923,044 disclosure) + ($3,228 reporting)].

Estimated Annual Non-Labor Cost: $4,642,347

(a) Recordkeeping

Staff believes that the capital and start-up costs associated with the TSR's recordkeeping provisions are de minimis. Although staff believes that most affected entities would maintain the required records in the ordinary course of business, consistent with its prior analyses, staff estimates that the estimated 4,835 telemarketing entities subject to the Rule continue to spend an annual amount of $50 each on office supplies as a result of the Rule's recordkeeping requirements, for a total recordkeeping cost burden of $241,750.

(b) Disclosure

Applying the disclosure estimates of 1,215,946 hours to an estimated commercial calling rate of 6 cents per minute ($3.60 per hour), staff estimates a total of $4,377,406 in telephone charges.[45] Thus, total capital and/or other non-labor costs are $4,619,156 ($241,750 (office supplies)) + $4,377,406 (telephone charges)).

Request for Comments

Pursuant to Section 3506(c)(2)(A) of the PRA, the FTC invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency'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 maintaining records and providing disclosures to consumers. All comments must be received on or before June 21, 2022.

You can file a comment online or on paper. For the FTC to consider your comment, we must receive it on or before June 21, 2022. Write ''Telemarketing Sales Rule; PRA Comment: FTC File No. P072108'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including the *https://www.regulations.gov* website.

Due to the public health emergency in response to the COVID–19 outbreak and the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. We encourage you to submit your comments online through the *https://www.regulations.gov* website.

If you prefer to file your comment on paper, write ''Telemarketing Sales Rule; PRA Comment: FTC File No. P072108'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex J), Washington, DC 20580; or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW, 5th Floor, Suite 5610 (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Because your comment will become publicly available at *https://www.regulations.gov,* you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not include any sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number, or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''trade secret or any commercial or financial information which . . . . is privileged or confidential'' —as provided by Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including in particular competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,'' and must comply with FTC Rule 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at *www.regulations.gov,* we cannot redact or remove your comment unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding, as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before June 21, 2022. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/site-information/privacy-policy.*

Josephine Liu,

Assistant General Counsel for Legal Counsel.

[FR Doc. 2022–08330 Filed 4–18–22; 8:45 am]

BILLING CODE 6750–01–P

[44] This figure is derived from the mean hourly wage shown for Telemarketers. *See supra* note 42. It is applied additionally to the ensuing calculation of reporting labor cost regarding the Registry operator.

[45] Staff believes that other non-labor costs would be incurred largely by affected entities in the ordinary course of business and, beyond that, would not materially exceed those ordinary costs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0553]

Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act; Draft Guidance for FDA Staff and Stakeholders; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for FDA staff and stakeholders entitled ''Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act.'' This draft guidance, when finalized, will explain our current thinking on the approach we generally intend to take when we evaluate the public health importance of a food allergen other than milk, eggs, fish, Crustacean shellfish, tree nuts, wheat, peanuts, soybean, and sesame (non-listed food allergen). (In April 2021, the Food Allergy Safety, Treatment, Education, and Research Act of 2021 amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add sesame to the definition of ''major food allergen.'' This statutory requirement goes into effect on January 1, 2023). We are also announcing an opportunity for public comment on our proposed collection of information. This draft guidance is not final nor is it in effect at this time.

DATES: Submit either electronic or written comments on the draft guidance by August 17, 2022 to ensure that we consider your comment on this draft guidance before we begin work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by August 17, 2022.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions)*: Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–N–0553 for ''Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' We will review this copy, including the claimed confidential information, in our consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Compliance Policy Staff, Office of Compliance (HFS–605), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance: Stefano Luccioli, Office of Compliance (HFS–605), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1283, *CFSANCompliancepolicy@fda.hhs.gov;* or Alexandra Jurewitz, Office of Regulations and Policy (HFS–024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

With regard to the proposed collection of information: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Food allergy can be broadly defined as an adverse health effect arising from a specific immune response that occurs reproducibly on exposure to a given food. A food allergen is the food or component(s) (often a protein) of a food that elicits specific immunologic reactions. While many different types of food allergies have been identified, food allergies that are most studied and understood clinically are those due to immunoglobulin E antibodies (IgE) that cause the body to release inflammatory chemicals. The most severe and immediately life-threatening food allergies are those that are mediated by

IgE and are capable of triggering anaphylaxis, which can be fatal. The focus of the draft guidance is IgE-mediated food allergy.

In general, the regulatory framework of the FD&C Act and our regulations implementing the FD&C Act broadly apply to the production of food that is or contains a food allergen through statutory and regulatory provisions regarding: (1) Food labeling; (2) food production (*e.g.,* manufacturing, processing, packing, and holding food); and (3) the safety of substances added to food. The Food Allergen Labeling and Consumer Protection Act of 2004 amended the FD&C Act to provide us with additional, specific authority regarding the labeling of a food (other than a raw agricultural commodity) that bears or contains a ''major food allergen.'' Under section 403(w) of the FD&C Act (21 U.S.C. 343(w)), a food is misbranded if it contains a major food allergen and fails to declare that major food allergen as specified on its label using the major food allergen's common or usual name. Section 201(qq)(1) of the FD&C Act (21 U.S.C. 321(qq)(1)) defines a ''major food allergen,'' in part, as any of the following: Milk, eggs, fish (*e.g.,* bass, flounder, or cod), Crustacean shellfish, tree nuts (*e.g.,* almonds, pecans, or walnuts), wheat, peanuts, and soybean. In April 2021, the Food Allergy Safety, Treatment, Education, and Research Act of 2021 amended section 201(qq) of the FD&C Act to add sesame to the definition of ''major food allergen.'' This amendment applies to ''any food that is introduced or delivered for introduction into interstate commerce on or after January 1, 2023'' (Pub. L. 117–11).

We are announcing the availability of a draft guidance for FDA staff and stakeholders entitled ''Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act.'' We are issuing the draft guidance consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

The draft guidance discusses: (1) The scientific factors that we would generally intend to consider when evaluating the public health importance of a non-listed food allergen; (2) other information, relevant to the labeling and production of food containing the food allergen, that we would generally intend to consider when evaluating the public health importance of a non-listed food allergen; and (3) our tentative recommendations for how to identify and evaluate the body of evidence applicable to an evaluation of the public health importance of a non-listed food allergen.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501–3521), 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 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.

Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0191—Revision

The draft guidance, when finalized, will describe our current thinking on the approach we generally intend to take when we evaluate the public health importance of a non-listed food allergen. Respondents who are interested in asking FDA to evaluate a food or component of food as a food allergen of public health importance may submit information relevant to their request in accordance with § 10.30 (21 CFR 10.30). We recommend that the submitted information include data demonstrating that the food allergy is IgE-mediated and data for prevalence, severity, and potency, as described in the draft guidance.

Description of respondents: The respondents to this collection of information are any persons who file citizen petitions under 21 CFR 10.30, which may include manufacturers and packers of packaged foods sold in the United States that may contain a non-listed food allergen and individuals and organizations interested in evaluating a food or component of food as a food allergen of public health importance. Respondents are from the private sector (for-profit businesses and non-profit entities).

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Avg. burden per response	Total hours
Submitting data for evidence of IgE-mediated food allergy, prevalence, severity, and potency; 10.30	1	1	1	80	80

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

We base these estimates on our experience with reviewing and evaluating data for food allergens. We estimate that one respondent will spend approximately 80 hours developing and

submitting the information to FDA each year.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 10 have been approved under OMB control number 0910–0191. The collections of information in 21 CFR part 101 have been approved under OMB control number 0910–0381. The collections of information in section 403(w) of the FD&C Act have been approved under OMB control number 0910–0792. The collections of information in 21 CFR part 117 have been approved under OMB control number 0910–0751. The collections of information for Form FDA 3800 have been approved under OMB control number 0910–0645. The collections of information for Form FDA 3500 have been approved under OMB control number 0910–0291. The collections of information in 21 CFR 70.25, 71.1, 170.36, 171.1, 172, 173, 179, and 180 have been approved under OMB control number 0910–0016.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/FoodGuidances*, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents*, or *https://www.regulations.gov*. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: April 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08303 Filed 4–18–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0030]

Fresenius Kabi USA, LLC, et al.; Withdrawal of Approval of Five Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on February 28, 2022. The document announced the withdrawal of approval of five abbreviated new drug applications (ANDAs) from multiple applicants as of March 30, 2022. The document indicated that FDA was withdrawing approval of the following ANDA after receiving a withdrawal request from Jiangsu Hengrui Pharmaceuticals Co., Ltd., U.S. Agent, Venus Pharmaceutical Laboratories Inc., 506 Carnegie Center, Suite 100, Princeton, NJ 08540: ANDA 091008, Gabapentin Capsules, 100 milligrams (mg), 300 mg, and 400 mg. Before FDA withdrew the approval of this ANDA, Jiangsu Hengrui Pharmaceuticals Co., Ltd., informed FDA that it did not want the approval of the ANDA withdrawn. Because Jiangsu Hengrui Pharmaceuticals Co., Ltd., timely requested that approval of this ANDA not be withdrawn, the approval of ANDA 091008 is still in effect.

FOR FURTHER INFORMATION CONTACT: Martha Nguyen, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1676, Silver Spring, MD 20993–0002, 240–402–6980, *Martha.Nguyen@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 28, 2022 (87 FR 11079), appearing on page 11079 in FR Doc. 2022–04153, the following correction is made:

On page 11079, in the table, the entry for ANDA 091008 is removed.

Dated: April 13, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08299 Filed 4–18–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0317]

Yvelice Villaman-Bencosme: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) permanently debarring Yvelice Villaman-Bencosme from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Yvelice Villaman-Bencosme was convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of a drug product under the FD&C Act. Ms. Villaman-Bencosme was given notice of the proposed permanent debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of December 13, 2021 (30 days after receipt of the notice), Ms. Villaman-Bencosme had not responded. Ms. Villaman-Bencosme's failure to respond and request a hearing constitutes a waiver of her right to a hearing concerning this action.

DATES: This order is applicable April 19, 2022.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or at *https://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM–4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743, *debarments@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(a)(2)(A) of the FD&C Act (21 U.S.C. 335a(a)(2)(A)) requires debarment of an individual from providing services in any capacity to a person that has an approved or pending drug product application if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act. On March 19, 2021, Ms. Villaman-Bencosme was convicted as defined in section 306(l)(1) of the FD&C Act when judgment was entered against her in the U.S. District Court for the Southern District of Florida-Miami Division, after her plea of guilty, to one count of Conspiracy to Commit Wire Fraud in violation of 18 U.S.C. 1349.

The factual basis for this conviction is as follows: Ms. Villaman-Bencosme was a licensed medical doctor who served as a clinical investigator at Unlimited Medical Research, LLC from about September 2013 through June 2016. Ms. Villaman-Bencosme conspired with others to unlawfully enrich herself by making materially false representations about clinical trials; fabricating data and the participation of subjects in those clinical trials; concealing from FDA, sponsors, and contract research organizations the fact that the data and participation of subjects had been