

their underlying persistent cancer pain. From May 2012 and continuing until December 2015, Mr. Rowan participated in a conspiracy whereby employees of Insys bribed medical practitioners in various States to get those practitioners to increase prescribing SUBSYS to their patients, many of whom did not have cancer. Mr. Rowan, along with his co-conspirators, measured the effect of these bribes on each practitioner's prescribing habits and on the revenue that each bribed practitioner generated for Insys. Mr. Rowan, along with his co-conspirators, reduced or eliminated bribes paid to those practitioners who failed to meet the minimum prescription requirements or failed to generate enough revenue to justify additional bribes.

To further this conspiracy, Mr. Rowan was involved in a scheme with his co-conspirators whereby Insys executives conspired to mislead and defraud health insurance providers to ensure those providers approved payment for SUBSYS. Insys achieved this goal by establishing the "Insys Reimbursement Center," which was designed to shift the burden of seeking prior authorization for SUBSYS from practitioners to Insys. This allowed Insys to determine what medical information was presented to insurers. Mr. Rowan and his co-conspirators directed Insys employees to mislead insurers to obtain payment authorization.

As a result of this conviction, FDA sent Mr. Rowan by certified mail on August 3, 2020, a notice proposing to permanently debar him from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(B) of the FD&C Act, that Mr. Rowan was convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act. The proposal also offered Mr. Rowan an opportunity to request a hearing, providing him 30 days from the date of receipt of the letter in which to file the request, and advised him that failure to request a hearing constituted an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Mr. Rowan received the proposal on August 7, 2020. He did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived his opportunity for a hearing and any contentions concerning his debarment (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and

Animal Food Operations, under section 306(a)(2)(B) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Mr. Rowan has been convicted of a felony under Federal law for conduct otherwise relating to the regulation of a drug product under the FD&C Act.

As a result of the foregoing finding, Mr. Rowan is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(B) and 306(c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Mr. Rowan, in any capacity during his debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Rowan provides services in any capacity to a person with an approved or pending drug product application during his period of debarment, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act (21 U.S.C. 335b(a)(7))). In addition, FDA will not accept or review any abbreviated new drug application from Mr. Rowan during his period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of section 306 of the FD&C Act, a "drug product" is defined as a drug subject to regulation under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382) or under section 351 of the Public Health Service Act (42 U.S.C. 262) (see section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Any application by Mr. Rowan for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2020-N-1412 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at <https://www.regulations.gov> or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: December 28, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020-29045 Filed 12-31-20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1129]

Agency Information Collection Activities; Proposed Collection; Comment Request; National Agriculture and Food Defense Strategy Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 the information collection requirements for a voluntary survey for the Department of Health and Human Services (HHS), the U.S. Department of Agriculture (USDA), and the Department of Homeland Security (DHS), which will inform the FDA Food Safety Modernization Act (FSMA), National Agriculture and Food Defense Strategy (NAFDS) Report to Congress. The proposed survey will be used to determine what food defense activities, if any, State, local, territorial, and/or tribal (SLTT) agencies have completed to date. The information will be compared to the initial baseline data collected by State(s) in 2018.

DATES: Submit either electronic or written comments on the collection of information by March 5, 2021.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 5, 2021. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 5, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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-2018-N-1129 for "Agency Information Collection Activities; Proposed Collection; Comment Request; National Agriculture and Food Defense Strategy Survey." Received comments, those filed in a timely manner (see **ADDRESSES**), 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." The Agency will review this copy, including the claimed confidential information, in its 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.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrahi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the 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, 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.

National Agriculture and Food Defense Strategy Survey

OMB Control Number 0910-0855—Extension

We are seeking OMB approval of the NAFDS under section 108 of FSMA. This is a voluntary survey of SLTT governments intended to gauge government activities in food and agriculture defense from intentional contamination and emerging threats. The collected information will be included in the mandatory NAFDS followup Report to Congress. The authority for us to collect the information derives from the Commissioner of Food and Drugs' authority provided in section 1003(d)(2)(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(c)).

Protecting the nation's food and agriculture supply against intentional contamination and other emerging threats is an important responsibility shared by SLTT governments as well as private sector partners. On January 4, 2011, the President signed into law FSMA. FSMA focuses on ensuring the safety of the U.S. food supply by shifting the efforts of Federal regulators from response to prevention and recognizes the importance of strengthening existing collaboration among all stakeholders to achieve common public health and security goals. FSMA identifies some key priorities for working with partners in areas such as reliance on Federal, State, and local agencies for inspections; improving foodborne illness surveillance; and leveraging and enhancing State and local food safety and defense capacities. Section 108 of FSMA (NAFDS) requires HHS and USDA, in coordination with DHS, to work together with State, local,

territorial, and tribal governments to monitor and measure progress in food defense.

In 2015, the initial NAFDS Report to Congress detailed the specific Federal response to food and agriculture defense goals, objectives, key initiatives, and activities that HHS, USDA, DHS, and other stakeholders planned to accomplish to meet the objectives outlined in FSMA. The NAFDS charts a direction for how Federal Agencies, in cooperation with SLTT governments and private sector partners, protect the nation's food supply against intentional contamination. Not later than 4 years after the initial NAFDS Report to Congress (2015), and every 4 years thereafter (*i.e.*, 2019, 2023, 2027, etc.), HHS, USDA, and DHS are required to revise and submit an updated report to the relevant committees of Congress.

FDA is the Agency primarily responsible for obtaining the information from Federal and SLTT

partners to complete the NAFDS Report to Congress. An interagency working group will conduct the survey and collect and update the NAFDS as directed by FSMA, including developing metrics and measuring progress for the evaluation process.

The survey of Federal and State partners will be used to determine what food defense activities, if any, Federal and/or SLTT agencies have completed (or are planning on completing) from 2021 to 2025. Planning for the local, territorial, and tribal information collections will commence during this period of renewal. The survey will continue to be repeated approximately every 2 to 4 years, as described in section 108 of FSMA. The NAFDS survey is being administered for the purpose of monitoring progress in food and agricultural defense by government agencies.

A purposive sampling strategy is employed, such that the government

agencies participating in food and agricultural defense are asked to respond to the voluntary survey. Food defense leaders responsible for conducting food defense activities during a food emergency for their jurisdiction are identified and will receive an emailed invitation to complete the survey online; they will be provided with a web link to the survey. The survey will be conducted electronically on the *FDA.gov* web portal, and results will be analyzed by the interagency working group.

Description of Respondents:

Respondents to this collection are SLTT government representatives (survey respondents) who are food defense leaders responsible for conducting food defense activities during a food emergency for their jurisdictions.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
SLTT Surveys	500	1	500	0.33 (20 minutes)	165

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

The FDA Office of Partnerships reviewed the questionnaire and provided the estimate of time to complete the survey. The total burden is based on our previous experiences conducting surveys. The burden has been revised to reflect the total number of states and possible number of local, tribal, and territorial entities that may partake of the survey. Based on a review of the information collection since our last request for OMB approval, we have increased our burden estimate by 149 hours (from 16.17 to 165 hours) and 451 respondents (from 49 to 500 respondents).

Dated: December 29, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2020–D–1825 and FDA–2020–D–1138]

Guidance Documents Related to Coronavirus Disease 2019; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of FDA guidance documents related to the Coronavirus Disease 2019 (COVID–19) public health emergency (PHE). This notice of availability (NOA) is pursuant to the process that FDA announced, in the **Federal Register** of March 25, 2020, for making available to the public COVID–19-related guidances. The guidances identified in this notice address issues related to the COVID–19 PHE and have been issued in accordance with the process announced in the March 25, 2020, notice. The guidances have been implemented without prior comment, but they remain subject to comment in accordance with the Agency's good guidance practices.

DATES: The announcement of the guidances is published in the **Federal Register** on January 4, 2021.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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>.