entry, where the person has no other conviction or program entry under Section 19, where it has been five years since the conviction or program entry (30 months in the case of a person 21 or younger as described above) and which does not involve an insured financial institution or insured credit union is considered *de minimis.* Simple theft excludes burglary, forgery, robbery, identity theft, and fraud.

Convictions or program entries for the use of a fake, false or altered identification card:

The use of a fake, false or altered identification card used by person under the legal age for the purpose of obtaining or purchasing alcohol, or used for the purpose of entering a premise where alcohol is served but for which age appropriate identification is required, provided that there is no other conviction or program entry for a covered offense, will be considered *de minimis.*

Any person who meets the criteria under (5) above shall be covered by a fidelity bond to the same extent as others in similar positions, and shall disclose the presence of the conviction or program entry to all insured institutions in the affairs of which he or she intends to participate.

Further, no conviction or program entry for a violation of the Title 18 sections set out in 12 U.S.C. 1829(a)(2) can qualify under any of the *de minimis* exceptions to filing set out in 5 above.

C. Procedures

When an application is required, forms and instructions should be obtained from, and the application filed with, the appropriate FDIC Regional Director. The application must be filed by an insured institution on behalf of a person (bank-sponsored) unless the FDIC grants a waiver of that requirement (individual waiver). Such waivers will be considered on a case-by-case basis where substantial good cause for granting a waiver is shown. The appropriate Regional Office for a bank-sponsored application is the office covering the state where the bank's home office is located. The appropriate Regional Office for an individual filing for a waiver of the institution filing requirement is the office covering the state where the person resides.

D. Evaluation of Section 19 Applications

The essential criteria in assessing an application are whether the person has demonstrated his or her fitness to participate in the conduct of the affairs of an insured institution, and whether the affiliation, ownership, control or participation by the person in the conduct of the affairs of the insured institution may constitute a threat to the safety and soundness of the insured institution or the interests of its depositors or threaten to impair public confidence in the insured institution. In determining the degree of risk, the FDIC will consider, in conjunction with the factors set out in 12 CFR 308.157:

(1) Whether the conviction or program entry and the specific nature and circumstances of the offense are a criminal offense under Section 19;

(2) Whether the participation directly or indirectly by the person in any manner in the conduct of the affairs of the insured institution constitutes a threat to the safety and soundness of the insured institution or the interests of its depositors or threatens to impair public confidence in the insured institution;

(3) Evidence of rehabilitation including the person's reputation since the conviction or program entry, the person's age at the time of conviction or program entry, and the time that has elapsed since the conviction or program entry;

(4) The position to be held or the level of participation by the person at an insured institution;

(5) The amount of influence and control the person will be able to exercise over the management or affairs of an insured institution;

(6) The ability of management of the insured institution to supervise and control the person's activities;

(7) The level of ownership the person will have of the insured institution;

(8) The applicability of the insured institution's fidelity bond coverage to the person; and

(9) Any additional factors in the specific case that appear relevant including but not limited to the opinion or position of the primary Federal and/or state regulator.

The foregoing criteria will also be applied by the FDIC to determine whether the interests of justice are served in seeking an exception in the appropriate court when an application is made to terminate the ten-year ban under 12 U.S.C. 1829(a)(2) for certain Federal offenses, prior to its expiration date.

Some applications can be approved without an extensive review because the person will not be in a position to constitute any substantial risk to the safety and soundness of the insured institution. Persons who will occupy clerical, maintenance, service, or purely administrative positions, generally fall into this category. A more detailed analysis will be performed in the case of persons who will be in a position to influence or control the management or affairs of the insured institution. All approvals and orders will be subject to the condition that the person shall be covered by a fidelity bond to the same extent as others in similar positions. In cases in which a waiver of the institution filing requirement has been granted to an individual, approval of the application will also be conditioned upon that person disclosing the presence of the conviction(s) or program entry(ies) to all insured institutions in the affairs of which he or she wishes to participate. When deemed appropriate, bank sponsored applications are to allow the person to work in a specific job at a specific bank and may also be subject to the condition that the prior consent of the FDIC will be required for any proposed significant changes in the person's duties and/or responsibilities. In the case of bank applications such proposed changes may, in the discretion of the Regional Director, require a new application. In situations in which an approval has been granted for a person to participate in the affairs of a particular insured institution and who subsequently seeks to participate at another insured depository institution, another application must be submitted.

By order of the Board of Directors, July 19, 2018.

Dated at Washington, DC, on July 19, 2018.

By order of the Board of Directors.

Valerie Best,

Assistant Executive Secretary.

[FR Doc. 2018–16634 Filed 8–2–18; 8:45 am]

BILLING CODE 6714–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1093]

Agency Information Collection Activities; Proposed Collection; Comment Request; Food Additive Petitions and Investigational Food Additive Exemptions

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 provisions of our regulations regarding Food Additive Petitions and Investigational Food Additive Exemptions.

DATES: Submit either electronic or written comments on the collection of information by October 2, 2018.

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 October 2, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of October 2, 2018. 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–2012–N–1093 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Food Additive Petitions and Investigational Food Additive Exemptions.'' 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.

- 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.gpo.gov/fdsys/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.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), 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.

Food Additive Petitions and Investigational Food Additive Exemptions—21 CFR 570.17, 571.1, and 571.6

OMB Control Number 0910–0546—Extension

Section 409(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 348(a)) provides that a food additive shall be deemed to be unsafe unless its use is permitted by a regulation which prescribes the condition(s) under which it may safely be used, or unless it is exempted by

regulation for investigational use. Section 409(b) of the FD&C Act (21 U.S.C. 348(b)) specifies the information that must be submitted by a petitioner to establish the safety of a food additive and to secure the issuance of a regulation permitting its use.

To implement the provisions of § 409 of the FD&C Act, we issued procedural regulations under 21 CFR part 571. These procedural regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broader terms by the FD&C Act. The regulations add no substantive requirements to those indicated in the FD&C Act, but attempt to explain these requirements and provide a standard format for submission to speed processing of the petition. Labeling requirements for food additives intended for animal consumption are also set forth in various regulations contained in 21 CFR parts 501, 573, and 579. The labeling regulations are considered by FDA to be cross-referenced to § 571.1, which is the subject of this same OMB clearance for food additive petitions.

With regard to the investigational use of food additives, § 409(j) of the FD&C Act (§ 409(j)) (21 U.S.C. 348(j)) provides that any food additive, or any food bearing or containing such an additive, may be exempted from the requirements of this section if intended solely for investigational use by qualified experts. Investigational use of a food additive is typically to address the safety and/or intended physical or technical effect of the additive.

To implement the provisions of § 409(j), we issued regulations under 21 CFR 570.17. These regulations are designed to specify more thoroughly the information that must be submitted to meet the requirement set down in broad terms by the FD&C Act. Labeling requirements for investigational food additives are also set forth in various regulations contained in 21 CFR 501. The labeling regulations are considered by FDA to be cross-referenced to § 570.17, which is the subject of this same OMB clearance for investigational food additive files.

The information collected is necessary to protect the public health. We use the information submitted by food manufacturers or food additive manufacturers to ascertain whether the data establish the identity of the substance, justify its intended effect in/on the food, and establish that its intended use in/on food is safe.

Description of Respondents: Respondents to this collection of information are food manufacturers or food additive manufacturers.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Food Additive Petitions:					
571.1(c) Moderate Category	12	1	12	3,000	36,000
571.1(c) Complex Category	12	1	12	10,000	120,000
571.6 Amendment of Petition	2	1	2	1,300	2,600
Investigational Food Additive Files:					
570.17 Moderate Category	4	1	4	1,500	6,000
570.17 Complex Category	5	1	5	5,000	25,000
Total Hours					189,600

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

We base our estimate of the total annual responses on submissions received during fiscal years 2016 and 2017. We base our estimate of the hours per response upon our experience with the petition and filing processes.

§ 571.1(c) Moderate Category: For a food additive petition without complex chemistry, manufacturing, efficacy or safety issues, the estimated time requirement per petition is approximately 3,000 hours. We estimate that, annually, 12 respondents will each submit 1 such petition, for a total of 36,000 hours.

§ 571.1(c) Complex Category: For a food additive petition with complex chemistry, manufacturing, efficacy and/or safety issues, the estimated time requirement per petition is approximately 10,000 hours. We estimate that, annually, 12 respondents will each submit 1 such petition, for a total of 120,000 hours.

§ 571.6: For a food additive petition amendment, the estimated time requirement per petition is approximately 1,300 hours. We estimate that, annually, two respondents will each submit one such amendment, for a total of 2,600 hours.

§ 570.17 Moderate Category: For an investigational food additive file without complex chemistry, manufacturing, efficacy, or safety issues, the estimated time requirement per file is approximately 1,500 hours. We estimate that, annually, four respondents will each submit one such file, for a total of 6,000 hours.

§ 570.17 Complex Category: For an investigational food additive file with complex chemistry, manufacturing, efficacy, and/or safety issues, the estimated time requirement per file is approximately 5,000 hours. We estimate that, annually, five respondents will each submit one such file, for a total of 25,000 hours.

The burden for this information collected has not changed since the last OMB approval.

Dated: July 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–16616 Filed 8–2–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0405]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device Recall Authority

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