The online survey will be broken into two main parts: (1) A cross-sectional survey designed to capture HCP observations from the medical conference and (2) an experimental study designed to assess how data disclosures and exhibit booth representative background influence HCP perceptions of promoted prescription drugs. The cross-sectional part of the survey will contain a series of close- and open-ended questions. The experimental study part of the survey will ask participants to view a brief video simulating a conference exhibit hall interaction between an HCP attendee and a booth employee and then answer questions about a fictitious prescription drug featured in the video. Table 2 shows our proposed study design and sample size across 12 conferences.

TABLE 2—STUDY DESIGN AND TARGET SAMPLE SIZES

Disclosure	Booth employee background		Total
	Business	Medical	
Present	n = 92	n = 92	184
Absent	n = 92	n = 92	184
Total	184	184	368

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

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Screener	933	1	933	.08 (5 minutes)	74.64
Pretest	25	1	25	0.33 (20 minutes)	8.25
Main test	368	1	368	0.33 (20 minutes)	121.44
Total					204.33

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

III. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Mack, J. (March 2006). ''Effective Physician Marketing at Medical Meeting Exhibits.'' *Pharma Marketing News, 5(3).*
2. *Industry Standard Report (2014). ''Pharmaceutical Detailing: In-Person vs. Electronic vs. Phone.'' Retrieved from *https://www.isrreports.com/wp-content/uploads/2014/08/ISR-Pharmaceutical-Detailing-In-Person-vs.-Electronic-vs.-Phone-Preview-Aug2014.pdf.*
3. Steinman, M. A., G. M. Harper, M. M. Chren, et al (April 2007). ''Characteristics and Impact of Drug Detailing for Gabapentin.'' *PLoS Med, 4*(4), e134. *http://dx.doi.org/10.1371/journal.pmed.0040134.*
4. Adler, D., A. Sherman, and M. Walz (2017). ''Medical Conference Presence: Is it Worth it for Your Brand?'' Retrieved from *https://www.pharmavoice.com/article/2017-9-medical-conferences/.*
5. *FDA. Warning letters and notice of violation letters to pharmaceutical companies. Retrieved from *https://www.fda.gov/drugs/enforcement-activities-fda/warning-letters-and-notice-violation-letters-pharmaceutical-companies.*
6. Brock, T. C. (June 1965). ''Communicator-Recipient Similarity and Decision Change.'' *Journal of Personality & Social Psychology, 1,* 650–654.
7. Braunsberger, K. and J. M. Munch (1998). ''Source Expertise Versus Experience Effects in Hospital Advertising.'' *Journal of Services Marketing, 12*(1), 23–38.
8. Siemens, J. C., S. Smith, D. Fisher, and T. D. Jensen, (2008). ''Product Expertise Versus Professional Expertise: Congruency Between an Endorser's Chosen Profession and the Endorsed Product.'' *Journal of Targeting, Measurement and Analysis for Marketing, 16*(3), 159–168.
9. Pechmann, C. (1992). ''Predicting When Two-Sided Ads Will be More Effective Than One-Sided Ads: The Role of Correlational and Correspondent Inferences.'' *Journal of Marketing Research, 29*(4), 441–453.

Dated: September 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–20614 Filed 9–17–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1657]

Agency Information Collection Activities; Proposed Collection; Comment Request; Survey of Drug Product Manufacturing, Processing, and Packing Facilities

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a survey of drug product manufacturing, processing, and packing facilities.

DATES: Submit either electronic or written comments on the collection of information by November 17, 2020.

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 November 17, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 17, 2020. 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–2020–N–1657 for ''Survey of Drug Product Manufacturing, Processing and Packing Facilities.'' 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. 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. 3501–3521), 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 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.

Survey of Drug Product Manufacturing, Processing and Packing Facilities—21 CFR parts 210 and 211

OMB Control Number 0910–NEW

FDA has the responsibility to regulate the safety, as well as the efficacy and quality, of drugs in the United States. Under the Food and Drug Administration Safety and Innovation Act (FDASIA) enacted in 2012, the term current good manufacturing practice (CGMP) includes the implementation of oversight and controls over the manufacturing, processing, and packing of drugs to ensure quality, including managing the risk of, and establishing the safety of, raw materials used in the manufacture of drugs. The safety and availability of drugs can be affected by raw material suppliers, the material supply chain, and the facility's controls

over raw material quality. Risk management enables manufacturers to make proper choices and ensure the continued suitability of these materials and supply chains. The Agency needs to better understand how manufacturers, processors, and packers of drug products approach managing risks related to components, containers, and closures as well as the supply and distribution chains between the producers of raw materials and drug product manufacturers, processors, and packers. Such information will allow FDA to examine the potential economic impact of changes to regulations that govern the manufacturing, processing, and packing of drugs.

This is a one-time information collection, the primary purpose of which is to collect industry-wide data on how facilities that manufacture, process, and pack drug products for use in humans and/or animals ensure the quality of their operations, including their current risk management approaches and practices for ensuring the quality and suitability of the drug components, containers, and closures that they use. FDA intends to use this information to inform its economic analyses of potential updates to CGMPs for human and animal drug product manufacturing, processing, and packing facilities under 21 CFR parts 210 and 211. Survey respondents will be contacted by email or, if necessary, by regular mail. Respondents will be able to take the survey online or, if requested, they can return a hard copy by mail. FDA estimates the maximum burden of this collection of information as follows:

TABLE 1—ESTIMATED BURDEN HOURS FOR ONE-TIME DATA COLLECTION [1]

Type of respondent/facility	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Group 1: Facilities in United States engaged in drug manufacturing (in addition to other possible activities).	394	1	394	1.1	433
Group 2: Facilities in United States *not* engaged in manufacturing but engaged in other forms of drug processing or packing (e.g., labeling, repacking, etc.).	333	1	333	0.75 (45 minutes)	250
Group 3: Facilities outside United States engaged in drug manufacturing (in addition to other possible activities).	407	1	407	2.20	895
Group 4: Facilities outside United States *not* engaged in manufacturing but engaged in other forms of drug processing or packing (e.g., labeling, repacking, etc.).	261	1	261	1.5	392
Total	1,395		1,395		1,970

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

Burden hours are based on pretests of the survey and interviews with industry representatives and reflect the time required by each type of respondent to read the survey invitation and instructions and complete the survey questions. The total estimated one-time burden hours are 1,970.

Dated: September 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–20619 Filed 9–17–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Immunology Integrated Review Group; Innate Immunity and Inflammation Study Section.

Date: October 15–16, 2020.

Time: 8:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Tina McIntyre, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4202, MSC 7812, Bethesda, MD 20892, (301) 594–6375, *mcintyrt@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Neuroimmunology and Brain Tumors.

Date: October 15, 2020.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Samuel C. Edwards, Ph.D., Chief, Brain Disorders and Clinical Neuroscience, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5210, MSC 7846, Bethesda, MD 20892, (301) 435–1246, *edwardss@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: September 14, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–20578 Filed 9–17–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,