Board of Governors of the Federal Reserve System, February 10, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–03048 Filed 2–12–21; 8:45 am]

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FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting a proposal to extend for three years, without revision the Reporting, Recordkeeping, and Disclosure Provisions Associated with the Guidance on Response Programs for Unauthorized Access to Customer Information and Customer Notice (FR 4100; OMB No. 7100–0309).

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829. Office of Management and Budget (OMB) Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395–6974.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the PRA to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. The OMB inventory, as well as copies of the PRA Submission, supporting statements, and approved collection of information instrument(s) are available at *https://www.reginfo.gov/public/do/PRAMain.* These documents are also available on the Federal Reserve Board's public website at *https://www.federalreserve.gov/apps/reportforms/review.aspx* or may be requested from the agency clearance officer, whose name appears above.

Final Approval Under OMB Delegated Authority of the Extension for Three Years, Without Revision, of the Following Information Collection

Report title: Reporting, Recordkeeping, and Disclosure Provisions Associated with the Guidance on Response Programs for Unauthorized Access to Customer Information and Customer Notice.

Agency form number: FR 4100.

OMB control number: 7100–0309.

Frequency: On occasion.

Respondents: State member banks, bank holding companies (BHCs), affiliates and certain non-banking subsidiaries of BHCs, uninsured state agencies and branches of foreign banks, commercial lending companies owned or controlled by foreign banks, savings and loan holding companies, and Edge and agreement corporations.

Estimated number of respondents: Recordkeeping, 1; Reporting, 831; Disclosure, 831.

Estimated average hours per response: Recordkeeping, 24 hours; Reporting, 9 hours; Disclosure, 27 hours.

Estimated annual burden hours: Recordkeeping, 24 hours; Reporting, 7,479 hours; Disclosure, 22,437 hours.

General description of report: The FR 4100 is the Board's information collection associated with the Interagency Guidance on Response Programs for Unauthorized Access to Customer Information and Customer Notice (''ID-Theft Guidance'' or ''Guidance''). The ID-Theft Guidance was published in the **Federal Register** in March 2005.[1] The ID-Theft Guidance, which applies to financial institutions, was issued in response to developing trends in the theft and accompanying misuse of customer information. The Guidance includes certain voluntary reporting, recordkeeping, and disclosure provisions.

Legal authorization and confidentiality: The FR 4100 is authorized by section 501(b) of the Gramm-Leach-Bliley Act,[2] which requires the Board, the Federal Deposit Insurance Corporation, and the Office of the Comptroller of the Currency to establish appropriate standards for financial institutions to develop and implement an information security program designed to protect their customers' information and a response program that specifies actions to be taken when the institution suspects or detects that unauthorized individuals have gained access to customer information systems.

Because the provisions under the FR 4100 are contained in guidance, which is nonbinding, the provisions are voluntary.[3]

The disclosure provisions of FR 4100 are not confidential. The records maintained under recordkeeping provisions of FR 4100 would be maintained at each banking organization, and the Freedom of Information Act (''FOIA'') would only be implicated if the Board obtained such records as part of the examination or supervision of a banking organization. In the event the records are obtained by the Board as part of an examination or supervision of a financial institution, this information may be considered confidential pursuant to exemption 8 of the FOIA, which protects information contained in ''examination, operating, or condition reports'' obtained in the bank supervisory process. In addition, the information obtained by the Board under the FR 4100 may also be kept confidential under exemption 4 for the FOIA, which protects commercial or financial information obtained from a person that is privileged or confidential.[4]

Current actions: On October 14, 2020, the Board published a notice in the **Federal Register** (85 FR 65046) requesting public comment for 60 days on the extension, without revision, of the Reporting, Recordkeeping, and Disclosure Provisions Associated with the Guidance on Response Programs for Unauthorized Access to Customer Information and Customer Notice. The comment period for this notice expired on December 14, 2020. The Board did not receive any comments.

Board of Governors of the Federal Reserve System, February 10, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–03072 Filed 2–12–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0089]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

[1] *See* 70 FR 15736 (March 29, 2005).

[2] 15 U.S.C. 6801(b).

[3] *See* SR 18–5/CA 18–7: Interagency Statement Clarifying the Role of Supervisory Guidance (Sept. 11, 2018).

[4] 5 U.S.C. 552(b)(4).

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on March 5, 2021, from 9 a.m. Eastern Time to 3:30 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. The online web conference meeting will be available at the following link on the day of the meeting: *https://youtu.be/dG_NjxSYBkA.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2021–N–0089. The docket will close on March 4, 2021. Submit either electronic or written comments on this public meeting by March 4, 2021. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before February 24, 2021, to be provided to the committee. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 4, 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.

Comments received on or before February 24, 2021, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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–0089 for ''Vaccines and Related Biological Products; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' 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.'' FDA 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 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 the 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: Kathleen Hayes or Monique Hill, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6306, Silver Spring, MD 20993–0002, 301–796–7864 or 301–796–4620, respectively; *CBERVRBPAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/advisory-committees* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The Committee will meet in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2021 to 2022 influenza season.

FDA intends to make background material available to the public no later

than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/advisory-committees/advisory-committee-calendar.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions made to the Docket (see **ADDRESSES**) on or before February 24, 2021, will be provided to the committee. Comments received after February 24, 2021, and by March 4, 2021, will be taken into consideration by FDA. Oral presentations from the public will be scheduled between approximately 1:30 p.m. Eastern Time and 2:30 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 18, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 19, 2021.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Kathleen Hayes, *CBERVRBPAC@fda.hhs.gov,* at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/advisory-committees/about-advisory-committees/public-conduct-during-fda-advisory-committee-meetings* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 8, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–03014 Filed 2–12–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–5364]

Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised); Guidance for Industry; 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 a revised guidance for industry entitled ''Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised).'' This is a revision to the second edition of this final guidance, which issued in May 2020, and is intended to assist those required to submit cigarette plans for cigarette packages and cigarette advertisements by providing content, timing, and other recommendations related to those submissions. FDA is revising this guidance to reflect the December 2, 2020, court order that postponed the effective date of the final rule entitled ''Tobacco Products; Required Warnings for Cigarette Packages and Advertisements'' to January 14, 2022. Pursuant to the court order, this revised guidance strongly encourages entities to submit cigarette plans to FDA as soon as possible after publication of the final rule, and in any event, by March 16, 2021.

DATES: The announcement of the revised guidance is published in the **Federal Register** on February 16, 2021.

ADDRESSES: You may submit 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.*
- 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–2019–D–5364 for ''Submission of Plans for Cigarette Packages and Cigarette Advertisements (Revised).'' 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 office 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