vaccine-eligible children through the Vaccines for Children (VFC) program, along with schedules regarding dosing interval, dosage, and contraindications to administration of vaccines. Further, under provisions of the Affordable Care Act, section 2713 of the Public Health Service Act, immunization recommendations of the ACIP that have been approved by the Director of the Centers for Disease Control and Prevention and appear on CDC immunization schedules must be covered by applicable health plans.

Matters for Discussion: The agenda will include discussions on:
- Meningococcal vaccine; influenza;
- hepatitis vaccines; herpes zoster vaccine; varicella; yellow fever vaccine;
- mumps disease and vaccine; Dengue virus vaccines; Human Papillomavirus (HPV); Anthrax vaccine workgroup;
- Vaccine Adverse Event Reporting System (VAERS) and vaccine supply. A recommendation vote is scheduled for hepatitis vaccines and influenza. A Vaccines for Children (VFC) vote is scheduled for hepatitis vaccines.

Agenda items are subject to change as priorities dictate.

ACIP Charter: https://www.cdc.gov/vaccines/acip/committee/charter.html.

Contact Person for More Information: Stephanie Thomas, National Center for Immunization and Respiratory Diseases, CDC, 1600 Clifton Road NE., MS–A27, Atlanta, Georgia 30329, telephone 404/639–8836; Email ACIP@CDC.GOV.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

The meeting announced below concerns the Centers for Disease Control and Prevention (CDC) initial review of applications in response to Funding Opportunity Announcement (FOA) TS17–001, Identify and Characterize Potential Environmental Risk Factors for Amyotrophic Lateral Sclerosis (ALS), TS17–001.

Summary: This publication corrects a notice that was published in the Federal Register on May 4, 2017, Volume 82, No. 85, page 20895. The meeting time and date should read as follows:

Time and Date: 8:00 a.m.–6:00 p.m., EST, June 14, 2017 (Closed).

Contact Person for More Information: Oscar Tarragó, M.D., M.P.H., Scientific Review Officer, CDC, 4770 Buford Highway NE., Mailstop F63, Atlanta, Georgia 30341, Telephone: (770) 488–3492.

The Director, Management Analysis and Services Office, has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,
Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Federal Register Notice]

Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule.” This guidance is intended to assist persons who manufacture, package, sell, offer to sell, distribute, or import for sale and distribution within the United States newly regulated tobacco products, roll-your-own (RYO) tobacco, and cigarette tobacco in complying with the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), and FDA regulations.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: 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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, 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–2017–D–2834 for “Three-Month Extension of Certain Tobacco Product Compliance Deadlines Announced in the Final Deeming Rule.” 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 Division of Dockets Management 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 Division of Dockets Management. 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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submits written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT:

Deirdre Jurand, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, email: CTPhRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled “Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule.” This guidance is intended to assist persons who manufacture, package, sell, offer to sell, distribute, or import for sale and distribution within the United States newly regulated tobacco products, RYO tobacco, and cigarette tobacco in complying with the FD&C Act, as amended by the Tobacco Control Act, and FDA regulations. We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 [21 CFR 10.115]). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate given that the 3-month extension applies to provisions with imminent compliance deadlines ($ 10.115(g)(2)). We made this determination because FDA needs to communicate in a timely manner that the guidance provides a 3-month extension to the compliance deadlines for certain provisions under the final deeming rule that are set for as early as May 2017. Although this guidance document is immediately effective, it remains subject to comment in accordance with FDA’s GGP regulation.

The Tobacco Control Act (Pub. L. 111–31) granted FDA the authority to immediately regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, RYO, and smokeless tobacco products to protect the public health and to reduce tobacco use by minors.

The Tobacco Control Act also gave FDA the authority to issue a regulation deeming all other products that meet the statutory definition of a tobacco product to be subject to Chapter IX of the FD&C Act (section 901(b) (21 U.S.C. 387a(b)) of the FD&C Act). On May 10, 2016, FDA issued that rule, extending FDA’s tobacco product authority to all products that meet the definition of tobacco product in the law (except for accessories of newly regulated tobacco products), including electronic nicotine delivery systems, cigars, hookah, pipe tobacco, nicotine gels, dissolvables that were not already subject to the FD&C Act, and other tobacco products that may be developed in the future (81 FR 28974 at 28976) (“the final deeming rule”). Chapter IX of the FD&C Act now applies to newly regulated tobacco products, including sections 904(a)(1) and (4) (21 U.S.C. 387d(a)(1) and (4)) (ingredient listing, health document submissions), 903(a)(4) and (a)(8) (21 U.S.C. 387c(a)(4) and (a)(8)) (labeling requirements), 904(c)(1), 905(b), (c), (d), (h) (registration), (21 U.S.C. 387e(b), (c), (d), (h) 905(f)(1) (product listing), 907(a)(1)(B) (21 U.S.C. 387g(a)(1)(B)) (additional special rule), 911 (21 U.S.C. 387k) (modified risk claims), 904(a)(3) and 915 (21 U.S.C. 387o) (harmful and potentially harmful constituent reporting), and 920 (21 U.S.C. 387l) (labeling, recordkeeping, records inspection). The final rule also included several requirements that apply to a

1 "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products," 81 FR28974 [May 10, 2016].
subgroup of products referred to as “covered tobacco products.”

FDA is providing a 3-month extension that applies to effective dates and compliance deadlines for requirements under the final rule set for May 10, 2017, or later and to all categories of the newly regulated products, as well as the addictiveness warning requirement for RYO and cigarette tobacco.

The guidance represents the current thinking of the 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.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in section 910(c)(1)(A)(i) of the FD&C Act and 21 CFR part 1143 have been approved under OMB control number 0910–0768; the collections of information in section 905(j) of the FD&C Act have been approved under OMB control number 0910–0673; the collections of information in section 904(a)(4) of the FD&C Act have been approved under OMB control number 0910–0654; the collections of information in 21 CFR part 1107 have been approved under OMB control number 0910–0684; the collections of information in section 904(c)(1), 905(b),(c),(d), (h), and 905(i)(1) of the FD&C Act have been approved under OMB control number 0910–0650.

III. Electronic Access

Persons with access to the Internet may obtain an electronic version of the guidance at either https://www.regulations.gov or https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm.


Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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: National Institute of Mental Health Special Emphasis Panel, Development of Psychosocial Therapeutic and Preventive Interventions for Mental Disorders.

Date: June 2, 2017.
Time: 9:30 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).
Contact Person: David I. Sommers, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6134, MSC 6906, Bethesda, MD 20892, 301–443–7861, dsommers@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, Early Stage Testing of Pharmacologic or Device-based Interventions for the Treatment of Mental Disorders.

Date: June 7, 2017.
Time: 9:30 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).
Contact Person: David I. Sommers, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd., Room 6134, MSC 6906, Bethesda, MD 20892, 301–443–7861, dsommers@mail.nih.gov.

Name of Committee: National Institute of Mental Health Special Emphasis Panel, BRAIN Initiative: Research on the Ethical Implications of Advancements in Neurotechnology and Brain Science (R01) RFA.

Date: June 8, 2017.
Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).
Contact Person: Megan Kinnane, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, NIH, Neuroscience Center, 6001 Executive Blvd., Room 6148, MSC 6909, Rockville, MD 20852–9609, 301–402–6807, libbeym@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.242, Mental Health Research Grants; 93.281)

Dated: May 9, 2017.
Melanie J. Pantoja,
Program Analyst, Office of Federal Advisory Committee Policy.

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 (5 U.S.C. App.), 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.


Date: May 25, 2017.
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 (Telephone Conference Call).
Contact Person: Jingsheng Tuo, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5207, Bethesda, MD 20892, 301–451–8754, tuoj@nei.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.