material to patient or consumer audiences versus risk information that is material primarily to the prescriber or other health care providers? What data are available to answer this question? 5. What criteria should be used to determine which risk information that is material to patient or consumer audiences to include in the major statement for DTC prescription drug broadcast advertisements to best protect the public health? What data are available to answer this question? 6. What is the potential impact of including (or conversely, of not including), in the major statement for DTC prescription drug broadcast advertisements, additional language that states that there are other risks not included in the advertisement while simultaneously encouraging dialogue between patients and their health care providers? (For example, additional language could include, “This is not a full list of risks and side effects. Talk to your health care provider and read the patient labeling for more information.”) What data are available to answer this question? 7. What data are available on consumers’ comprehension of the difference between levels (i.e., severity) of risk? Would it be in the interest of public health to include a signal before the risk information that frames and categorizes the overall level of risk associated with the product? One approach may be to include an opening statement tailored to the risk profile of the drug. For example, drugs could be divided into three defined categories and include the corresponding opening statements: a. For drugs with severe, life-threatening risks: “[Drug] can cause severe, life-threatening reactions. These include . . . .” b. For drugs with serious but not life-threatening risks: “[Drug] can cause serious reactions. These include . . . .” c. For drugs with no severe or serious risks: “[Drug] can cause reactions. These include . . . .” 8. Should potential food and drug interactions be disclosed in DTC prescription drug broadcast advertisements, and if so, what criteria should be used to identify these interactions? FDA will consider all information and comments submitted.

III. References

The following references are on display in the Dockets Management Staff office (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at https://www.regulations.gov.


Leslie Kux,
Associate Commissioner for Policy.

[FR Doc. 2017–17563 Filed 8–18–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Charter Renewal of the National Vaccine Advisory Committee

AGENCY: National Vaccine Program Office, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services is hereby giving notice that the charter for the National Vaccine Advisory Committee (NVAC) has been renewed.


SUPPLEMENTARY INFORMATION: NVAC is a non-discretionary Federal advisory committee. The establishment of NVAC was mandated under Section 2105 (42 U.S.C. Section 300a–5) of the Public Health Service Act, as amended (PHS Act). The Committee is governed by provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463, as amended (5 U.S.C. App.). NVAC advises and makes recommendations to the Director, National Vaccine Program (NVP), on matters related to the Program’s responsibilities. The Assistant Secretary for Health is appointed to serve as the Director, NVP. To carry out its mission, NVAC (1) studies and recommends ways to encourage the availability of an adequate supply of safe and effective vaccination products in the United States; (2) recommends research priorities and other measures the Director of the NVP should take to enhance the safety and efficacy of vaccines; (3) advises the Director of the NVP in the implementation of Sections 2102 and 2103 of the PHS Act; and (4) identifies annually for the Director of the NVP the most important areas of governmental and non-governmental cooperation that should be considered in implementing Sections 2101 and 2103 of the PHS Act.

On July 21, 2017, the Acting Assistant Secretary for Health approved renewal of the NVAC charter with minor amendments. The new charter was effected and filed with the appropriate Congressional committees and Library of Congress on July 30, 2017. Renewal of the NVAC charter gives authorization for the Committee to continue to operate until July 30, 2019. A copy of the NVAC charter is available on the Web site for the National Vaccine Program Office at http://www.hhs.gov/nvpo/nvac. A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The Web site address for the FACA database is http://www.facadatabase.gov/.


Melinda Wharton,
Acting Director, National Vaccine Program Office.

[FR Doc. 2017–17527 Filed 8–18–17; 8:45 am]

BILLING CODE 4150–44–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Division of Behavioral Health; Office of Clinical and Preventive Services; Zero Suicide Initiative—Support

Announcement Type: New.
Catalog of Federal Domestic Assistance Number: 93.933.

Key Dates
Application Deadline Date: October 12, 2017.
Earliest Anticipated Start Date: November 1, 2017.
Signed Tribal Resolution Due Date: October 12, 2017.
Proof of Non-Profit Status Due Date: October 12, 2017.