IV. List of Recognized Standards

FDA maintains the current list of FDA Recognized Consensus Standards in a searchable database that may be accessed at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. FDA will be incorporating the modifications and revisions described in this notice into the database and, upon publication in the Federal Register, this recognition of consensus standards will be effective. FDA will be announcing additional modifications and revisions to the list of recognized consensus standards in the Federal Register, as needed, once a year, or more often if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to CDRHStandardsStaff@fda.hhs.gov. To be considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and electronic or mailing address of the requestor, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.


Leslie Kux,
Associate Commissioner for Policy.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

<table>
<thead>
<tr>
<th>Recognition No.</th>
<th>Title of standard ¹</th>
<th>Reference No. and date</th>
</tr>
</thead>
<tbody>
<tr>
<td>S. Tissue Engineering</td>
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</table>

¹ All standard titles in this table conform to the style requirements of the respective organizations.
disseminated at health care provider offices or pharmacies, and through the internet. See the guidance for industry entitled “Consumer-Directed Broadcast Advertisements,” available at http://www.fda.gov/ForIndustry/ FDABasicsforIndustry/ucm234622.htm.

From a public health standpoint, FDA is interested in helping to ensure that when firms choose to advertise directly to consumers and patients, such advertisements provide clear and useful information to that audience. There is concern that the major statement, as currently implemented in DTC broadcast advertisements for prescription drugs, is not fulfilling this purpose. Some believe it is often too long, which may result in reduced consumer comprehension, minimization of important risk information, and, potentially, therapeutic noncompliance caused by fear of side effects (Ref. 1). At the same time, there is concern that DTC broadcast advertisements do not include adequate risk information or that they leave out important information (Refs. 2 and 3).

The Office of Prescription Drug Promotion (OPDP) within FDA’s Center for Drug Evaluation and Research (CDER) is investigating through empirical research the effectiveness of a limited risks plus disclosure strategy to inform the Agency’s decision making in this area. (For more information about OPDP’s proposed study, see 79 FR 9217, February 18, 2014.) Through the research and through this request for information and comments, OPDP is exploring the usefulness of limiting the risks in the major statement for most DTC broadcast advertisements for prescription drugs to those that are severe (life-threatening), serious, or actionable, coupled with a disclosure to alert consumers that there are other product risks not included in the advertisement. (For example, a disclosure could be, “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.”)

For the purposes of this request for information and comments, please consider the following definitions:

- **Severe risk**—a serious risk that is life-threatening (see serious risk).
- **Serious risk**—the risk of reactions from using the drug that may result in inpatient hospitalization or prolonged existing hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect. Reactions that do not require hospitalization, cause a disability, or cause a birth defect may still be considered serious risks when, based on appropriate medical judgment, they may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes previously listed.

### 1. What data are available regarding the impact of the current approaches to communication of risk information in DTC prescription drug broadcast advertisements on consumer comprehension of the information in the advertisement, including the impact on comprehension of product benefits and risk information?

### 2. What are the potential effects of only including risks from the FDA-approved product labeling that are severe, serious, or actionable (as previously defined) in the major statements of DTC prescription drug broadcast advertisements? Are there other ways of characterizing which risks should be included in the major statement? Please explain.

### 3. When a DTC prescription drug broadcast advertisement presents information relating to the effectiveness of a prescription drug that does not have severe, serious, or actionable risks, what type of risk could be included in the major statement?

### 4. What criteria should be used to distinguish risk information that is most
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 300aa–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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Indian Health Service

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


Key Dates

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.