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

Recognition No.	Title of standard [1]	Reference No. and date
S. Tissue Engineering		
15–50	Standard Guide for Quantifying Cell Viability within Biomaterial Scaffolds	ASTM F2739–16.

[1] All standard titles in this table conform to the style requirements of the respective organizations.

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.

Dated: August 16, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–17603 Filed 8–18–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–2936]

Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements; Establishment of a Public Docket; Request for Information and Comments

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is establishing a public docket to assist with its development of recommendations regarding the communication of risk information in direct-to-consumer (DTC) broadcast advertisements for prescription drugs and biologics.

DATES: Although you can comment at any time, to ensure that the Agency considers your comment in our development of recommendations, submit either electronic or written information and comments by November 20, 2017.

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):* 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–2017–N–2936 for ''Content of Risk Information in the Major Statement in Prescription Drug Direct-to-Consumer Broadcast Advertisements.'' 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 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 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.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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: *Regarding human prescription drugs:* Julie Chronis, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3203, Silver Spring, MD 20993–0002, 301–796–1200.

Regarding human prescription biological products: Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

The prescription drug advertising regulations require that broadcast advertisements containing product claims include information relating to the advertised drug's major side effects and contraindications in either the audio or audio and visual parts of the advertisement (21 CFR 202.1(e)(1)); this is often called the *major statement.* The regulations also require that broadcast advertisements contain a brief summary of all necessary information related to side effects and contraindications or that ''adequate provision'' be made for dissemination of the approved package labeling in connection with the broadcast presentation (21 CFR 202.1(e)(1)). This requirement to make ''adequate provision'' is generally fulfilled when a firm gives consumers the option of obtaining the FDA-required labeling or other information via a toll-free telephone number, through print advertisements or product brochures, through information 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.
- *Actionable risk*—a risk the patient would know (*e.g.,* pre-existing condition or allergy) or recognize (*e.g.,* observable physical or mental symptom) and can act upon to help mitigate the risk (*e.g.,* get immediate medical help to prevent a bad outcome); for example, ''Stop using the product and get immediate medical help if you have swelling of the face, lips, tongue, or throat.''

However, we note that while some drug products may not have severe, serious, or actionable risks as described in this document, all DTC prescription drug broadcast advertisements are required to present a fair balance of risk information when presenting information relating to the effectiveness of the drug (21 CFR 202.1(e)(5)). Therefore, to avoid a misleading presentation regarding a drug's risk-benefit profile, prescription drug advertisements that provide information about a drug's effectiveness would be expected to contain some risk information, even if the risks are not severe, serious, or actionable.

II. Request for Information and Comments

Interested persons are invited to provide detailed information and comments on the content of risk information in DTC broadcast advertisements for prescription drugs. FDA is particularly interested in responses to the following questions:

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 types of risk could be included in the major statement?

4. What criteria should be used to distinguish risk information that is most

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*.

1. Delbaere, M. and M.C. Smith, ''Health Care Knowledge and Consumer Learning: The Case of Direct-to-Consumer Drug Advertising,'' *Health Marketing Quarterly,* vol. 23, issue 3, pp. 9–29, 2006.

2. Friedman, M. and J. Gould, ''Consumer Attitudes and Behaviors Associated With Direct-to-Consumer Prescription Drug Marketing,'' *Journal of Consumer Marketing,* vol. 24, issue 2, pp. 100–109, 2007.

3. Frosch, D.L., P.M. Krueger, R.C. Hornik, P.F. Cronholm, and F.K. Barg, ''Creating Demand for Prescription Drugs: A Content Analysis of Television Direct-to-Consumer Advertising,'' *The Annals of Family Medicine,* vol. 5, issue 1, pp. 6–13, 2007.

Dated: August 15, 2017.

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.

FOR FURTHER INFORMATION CONTACT: National Vaccine Program Office, U.S. Department of Health and Human Services, Room 715H, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201. Phone: (202) 690–5566; email: *nvac@hhs.gov.*

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/.*

Dated: August 14, 2017.

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.

Funding Announcement Number: HHS–2018–IHS–ZSI–0001.

Catalog of Federal Domestic Assistance Number: 93.933.

Key Dates

Application Deadline Date: October 12, 2017.

Review Date: October 16–20, 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.