FOR FURTHER INFORMATION CONTACT: Claudine Kavanaugh, Food and Drug Administration, Office of Foods and Veterinary Medicine, 10903 New Hampshire Ave., Bldg. 1, Rm. 3218, Silver Spring, MD 20993, 301–796–4647.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 27, 2018 (83 FR 30180), FDA announced that it would hold a public meeting entitled ''FDA's Comprehensive, Multi-Year Nutrition Innovation Strategy.'' The public meeting, which we held on July 26, 2018, was intended to give interested persons an opportunity to discuss FDA's Nutrition Innovation Strategy and to provide input on ways to modernize FDA's approach to better protect public health while removing barriers to industry innovation. We stated that the topics to be addressed at the meeting would include the following:

- Considering using a standard icon to denote the claim ''healthy'' on food labels.
- Creating a more efficient review strategy for evaluating qualified health claims on food labels.
- Discussing new or enhanced labeling statements or claims that could facilitate innovation to produce more healthful foods and more healthful consumer food choices.
- Modernizing the standards of identity to provide more flexibility for the development of healthier products, while making sure consumers have accurate information about these food products.
- Providing opportunities to make ingredient information more helpful to consumers.
- FDA's educational campaign for consumers about the updated Nutrition Facts label.

See 83 FR 30180 at 30181 to 30182.

The notice invited interested parties to provide information on these and other topics related to FDA's Nutrition Innovation Strategy. We asked that comments be submitted on or before August 27, 2018.

After the public meeting, we received several requests to extend the comment period. The requesters asserted that the time period of 32 days was insufficient to respond fully to FDA's specific request for comments and to ensure comprehensive public input and allow potential respondents to thoroughly evaluate and address pertinent issues.

We have considered the requests and are extending the comment period for another 45 days, until October 11, 2018. We believe that a 45-day extension allows adequate time for interested persons to submit comments while ensuring the continued forward progress of FDA's Nutrition Innovation Strategy.

Dated: August 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–18072 Filed 8–21–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2999]

Determination That DANOCRINE (Danazol) Capsules, 50 Milligrams, 100 Milligrams, and 200 Milligrams, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness Except the Indication of Fibrocystic Breast Disease, Which Was Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that DANOCRINE (danazol) Capsules, 50 milligrams (mg), 100 mg, and 200 mg, were not withdrawn from sale for reasons of safety or effectiveness, except with respect to the indication of fibrocystic breast disease that was withdrawn for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to suspend approval of abbreviated new drug applications (ANDAs) that refer to this drug product and have removed the indication for fibrocystic breast disease. This determination also will allow FDA to continue to approve ANDAs that refer to this drug as long as they meet relevant legal and regulatory requirements. However, the Agency will not accept or approve ANDAs for DANOCRINE (danazol) Capsules, 50 mg, 100 mg, and 200 mg that include fibrocystic breast disease as an indication.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

Under § 314.161(a)(2), the Agency must also determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness if ANDAs that referred to the listed drug have already been approved prior to its market withdrawal. If the Agency determines that a listed drug was withdrawn from sale for reasons of safety or effectiveness, and there are approved ANDAs that reference that listed drug, FDA will initiate a proceeding to determine whether the suspension of the ANDAs is also required (§ 314.161(d)).

DANOCRINE (danazol) Capsules, 50 mg, 100 mg, and 200 mg, is the subject of NDA 017557 held by Sanofi-Aventis, and initially approved on June 21, 1976. DANOCRINE is indicated for the treatment of endometriosis amenable to hormonal management, prevention of attacks of angioedema of all types (cutaneous, abdominal, and laryngeal) in males and females, and fibrocystic breast disease. Specifically, with respect to fibrocystic breast disease, the labeling states ''Most cases of fibrocystic breast disease may be treated by simple

measures (*e.g.,* padded brassieres and analgesics). In infrequent patients, symptoms of pain and tenderness may be severe enough to warrant treatment by suppression of ovarian function. DANOCRINE is usually effective in decreasing nodularity, pain, and tenderness. It should be stressed to the patient that this treatment is not innocuous in that it involves considerable alterations of hormone levels and that recurrence of symptoms is very common after cessation of therapy.''

DANOCRINE (danazol) Capsules, 50 mg, 100 mg, and 200 mg, were discontinued from sale in December 2004. FDA moved the product to the ''Discontinued Drug Product List'' section of the Orange Book at that time. In a letter dated October 17, 2011, Sanofi-Aventis requested the withdrawal of the DANOCRINE application. On July 19, 2013, the Agency issued a **Federal Register** notice withdrawing NDA 017557, the application for DANOCRINE, effective August 19, 2013.

After reviewing our records and based on the information we have at this time, FDA has determined that under § 314.161 DANOCRINE (danazol) Capsules, 50 mg, 100 mg, and 200 mg, were not withdrawn from sale for reasons of safety or effectiveness, except with respect to the indication for fibrocystic breast disease. Fibrocystic breast disease refers to mastalgia or breast pain caused by benign proliferative breast tissue. The term fibrocystic breast disease is no longer used, in part because it is not accurate to describe the condition as a disease when it is in fact the result of normal physiologic changes.

DANOCRINE (danazol) has been associated with two serious adverse reactions: hepatocellular injury (*i.e.,* hepatocellular injury, hepatocellular jaundice, and hepatic failure) and an increased risk of rhabdomyolysis in patients taking danazol and statins. These two adverse reactions were not yet recognized when DANOCRINE (danazol) was originally approved for fibrocystic breast disease in 1980. Both of these adverse reactions were added to the safety labeling for the product several years after the product was initially approved. In addition, androgenic adverse effects and a contraindication for use in women who are pregnant or attempting to become pregnant limit the utility of DANOCRINE (danazol) for the fibrocystic breast disease indication.

The Agency conducted a review of the benefit-risk profile for each indication of DANOCRINE (danazol). For the treatment of fibrocystic breast disease, the Agency concluded that the benefit-risk profile of the product is unfavorable given the risk of potentially serious adverse reactions and that the condition is a benign, non-disease state. In addition, many other treatment options exist for this condition, including dietary measures, use of supportive undergarments and pain relievers such as acetaminophen or non-steroidal anti-inflammatory drug products. Many of these treatment options present a very low risk of adverse reactions. For the indications of treatment of endometriosis amenable to hormone management and prevention of attacks of angioedema of all types (cutaneous, abdominal, and laryngeal) in males and females, the Agency has determined that DANOCRINE (danazol) continues to have a favorable benefit-risk profile.

Accordingly, the Agency will continue to list DANOCRINE (danazol) Capsules, 50 mg, 100 mg, and 200 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. All approved ANDAs have removed the fibrocystic breast disease indication from their labeling. In addition, FDA will continue to approve ANDAs that refer to DANOCRINE (danazol) Capsules as long as they meet relevant legal and regulatory requirements, but FDA will not accept or approve ANDAs that refer to this drug product and propose to include the fibrocystic breast disease indication.

Dated: August 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–18081 Filed 8–21–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Training in Primary Care Medicine and Dentistry

AGENCY: Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Training in Primary Care Medicine and Dentistry (ACTPCMD) will hold a public meeting. Information about ACTPCMD and the agenda for this meeting can be found on the ACTPCMD website at: *https://www.hrsa.gov/advisory-committees/primarycare-dentist/index.html.*

DATES: September 10, 2018, 9:00 a.m.–5:00 p.m. ET, and September 11, 2018, 8:30 a.m.–2:30 p.m. ET.

ADDRESSES: This meeting will be held in person and offer virtual access through teleconference and webinar. The address for the meeting is 5600 Fishers Lane, Rockville, Maryland 20857.

- *Conference call-in number:* 1–800–238–9007; Passcode: 532320.
- *Webinar link: https://hrsa.connectsolutions.com/actpcmd.*

FOR FURTHER INFORMATION CONTACT: Dr. Kennita Carter, Designated Federal Official (DFO), Division of Medicine and Dentistry, Bureau of Health Workforce, HRSA, 5600 Fishers Lane, 15N–116, Rockville, Maryland 20857; 301–945–3505; or *KCarter@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACTPCMD provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other matters of significance concerning the activities under section 747 of Title VII of the Public Health Service (PHS) Act, as it existed upon the enactment of Section 749 of the PHS Act in 1998. ACTPCMD prepares an annual report describing the activities of the Committee, including findings and recommendations made by the Committee concerning the activities under section 747, as well as training programs in oral health and dentistry. The annual report is submitted to the Secretary and Chairman and ranking members of the Senate Committee on Health, Education, Labor and Pensions, and the House of Representatives Committee on Energy and Commerce. The Committee also develops, publishes, and implements performance measures and guidelines for longitudinal evaluations of programs authorized under Title VII, Part C, of the PHS Act, and recommends appropriation levels for programs under this Part.

During the September 10–11, 2018, meeting, ACTPCMD will have follow-up discussions on PHS Act section 747 and oral health training programs, and finalize its recommendations on funding and appropriation levels to be included in its 16th report. In addition, the Committee will complete the 16th report and a pending report on promoting clinical trainee and faculty well-being and mitigating burnout. Agenda items are subject to change as priorities dictate.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested