distinguish the appearance of an MMA product? We also request comment about alternative labeling approaches that would display the required information with equal prominence but may result in lower costs.

6. The draft guidance describes procedures for manufacturers of drug products approved under new drug applications or biologics license applications to obtain an additional NDC for an MMA product. FDA is interested as to whether manufacturers of generic drugs approved under an abbreviated new drug application confront similar pricing issues such that it would be appropriate to provide guidance on a similar approach for generic drugs. To the extent that interested parties believe that different considerations should apply to such an approach for generic drugs from those described in the draft guidance, input is requested on that as well.

7. There are complex considerations that impact biosimilar development, market entry, and uptake. We are interested in the possible impacts of MMA products that are biological products on biosimilar development, market entry, and uptake.

8. Similarly, there are complex considerations impacting generic drug market entry. We are interested in the possible impacts of MMA products on generic drug development and market entry.

9. Are there voluntary steps a manufacturer may take in addition to the requirements in the DSCSA to ensure the security of the supply chain for products imported pursuant to the guidance?

10. Are there any potential risks associated with the importation of products as described in the draft guidance that could be addressed by a rulemaking? For example, to what extent, if any, are there additional procedures that might better protect against entities seeking to introduce counterfeit drugs in the United States? If so, please be specific about the potential risk and how it could be addressed through rulemaking.

III. Paperwork Reduction Act of 1995

FDA has tentatively concluded that there are no new collections of information in this draft guidance. This draft guidance refers to previously approved collections of information found in the FD&C Act and FDA regulations. 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). In accordance with the Paperwork Reduction Act, if FDA's tentative conclusion changes, prior to publication of any final guidance document FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent material modifications to those previously approved collections of information found in FDA regulations or guidances.

The collections of information in 21 CFR part 314 (new drug applications) have been approved under OMB control number 0910–0001; the collections of information in 21 CFR part 601 (biologics license applications) have been approved under OMB control number 0910–0338; the collections of information in 21 CFR part 207 (domestic and foreign facility registration, including assignment of an NDC) have been approved under OMB control number 0910–0045; the collections of information in 21 CFR part 1 (general enforcement regulations) have been approved under OMB control number 0910–0046; the collections of information in 21 CFR part 201 (labeling) have been approved under OMB control number 0910–0572; the collections of information pertaining to current good manufacturing practice requirements for finished pharmaceuticals and combination products under 21 CFR parts 4, 210, 211, 610, and 680 have been approved under OMB control numbers 0910–0139 and 0910–0834; and the collections of information pertaining to suspect product identification and notification under section 582 of the FD&C Act have been approved under OMB control number 0910–0806.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: December 11, 2019.

Brett P. Giroir,

Acting Commissioner of Food and Drugs.

[FR Doc. 2019–27475 Filed 12–18–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

The meeting will be open to the public. The open session will be videocast and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov/*).

Name of Committee: National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

Date: March 12, 2020.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: Strategic Discussion of NCI's Clinical and Translational Research Programs.

Place: National Institutes of Health, Building 31, Room 11A01, 31 Center Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sheila A. Prindiville, M.D., M.P.H. Director, Coordinating Center for Clinical Trials, National Institutes of Health, National Cancer Institute, Coordinating Center for Clinical Trials, 9609 Medical Center Drive, Room 6W136, Rockville, MD 20850, 240–276–6173, *prindivs@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/ctac/ctac.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: December 17, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–27582 Filed 12–20–19; 8:45 am]

BILLING CODE 4140–01–P