An ANDA holder who decides to seek a hearing must file the following: (1) a written notice of participation and request for a hearing (see **DATES** and **ADDRESSES**) and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing (see **DATES** and **ADDRESSES**). Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, the information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 (21 CFR 314.200) and in 21 CFR part 12.

The failure of an ANDA holder to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that ANDA holder not to avail itself of the opportunity for a hearing concerning CDER's proposal to withdraw approval of the ANDAs and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the ANDAs, and the drug products may not thereafter be lawfully marketed or delivered for introduction into interstate commerce. Any new drug product introduced or delivered for introduction into interstate commerce without an approved ANDA is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing (§ 314.200(g)). If a request for a hearing is not complete or is not supported, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing (§ 314.200(g)(1)).

All submissions under this notice of opportunity for a hearing must be filed in two copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.*

This notice is issued under section 505(e)(2) of the FD&C Act and under authority delegated to the Director of CDER by the Commissioner of Food and Drugs.

Dated: September 16, 2020.

**Patrizia Cavazzoni,**

*Acting Director, Center for Drug Evaluation and Research.*

[FR Doc. 2020–21186 Filed 9–24–20; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Meeting of the Secretary's Advisory Committee on Human Research Protections

**AGENCY:** Office of the Secretary, Office of the Assistant Secretary for Health, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** Pursuant to the Federal Advisory Committee Act, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP, the full meeting agenda, and instructions for linking to public access will be posted on the SACHRP website at *http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html.*

**DATES:** The meeting will be held on Tuesday, October 20th, 2020, from 11:00 a.m. until 4:30 p.m., and Wednesday, October 21, 2020, from 11:00 a.m. until 4:30 p.m. (times are tentative and subject to change). The confirmed times and agenda will be posted at on the SACHRP website when this information becomes available.

**ADDRESSES:** This meeting will be held via webcast. Members of the public may also attend the meeting via webcast. Instructions for attending via webcast will be posted one week prior to the meeting at *https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html.*

**FOR FURTHER INFORMATION CONTACT:** Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240–453–8141; fax: 240–453–6909; email address: *SACHRP@hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The SACHRP meeting will open to the public at 11:00 a.m., on Tuesday, October 20, 2020, followed by opening remarks from Dr. Jerry Menikoff, Director of OHRP and Dr. Stephen Rosenfeld, SACHRP Chair. The meeting will begin with presentation of recommendations on the interpretation of the public health surveillance exclusion, 45 CFR 46.102(l)(2) and 46.102(k). This will be followed by a panel review of ethical considerations regarding ''justice'' within 45 CFR 46, and how this concept may affect the actions of IRBs. The following day continues with a discussion of recommendations on risks to bystanders posed by the research setting. Other topics may be added; for the full and updated meeting agenda, see *http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html.*

The public will have an opportunity to comment to the SACHRP during the meeting's public comment session or by submitting written public comment. Persons who wish to provide public comment should review instructions at *https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html* and respond by midnight Wednesday, October 14, 2020, ET. Individuals submitting written statements as public comment should submit their comments to SACHRP at *SACHRP@hhs.gov.* Verbal comments will be limited to three minutes each.

Time will be allotted for public comment on both days. Note that public comment must be relevant to topics currently being addressed by the SACHRP.

Dated: September 18, 2020.

**Julia G. Gorey,**

*Executive Director, SACHRP, Office for Human Research Protections.*

[FR Doc. 2020–21232 Filed 9–24–20; 8:45 am]

**BILLING CODE 4150–28–P**