

prevention interventions, relatively little scientific or systematic work has been done to describe the nature and level of fatal violence associated with schools. Until NCIPC conducted the first nationwide investigation of violent deaths associated with schools, public health and education officials had to rely on limited local studies and estimated numbers to describe the extent of school-associated violent death.

SAVD is an ongoing surveillance system that draws cases from the entire United States in an attempt to capture all cases of school-associated violent deaths that have occurred. Investigators review public records and published press reports concerning each school-associated violent death. For each identified case, investigators also contact the corresponding law enforcement agency and speak with an official in order to confirm or reject the case as an SAVD, and to request a copy

of the official law enforcement report for confirmed SAVD cases.

In past years, investigators would interview an investigating law enforcement official (defined as a police officer, police chief, or district attorney), and a school official (defined as a school principal, school superintendent, school counselor, school teacher, or school support staff) who were knowledgeable about the case in question; however, moving forward, the interviews with these respondents will be eliminated, and instead CDC study personnel will abstract data from law enforcement reports to enter using a Data Abstraction Tool. Data to be abstracted from the law enforcement report include the following: Information on both the victim and alleged offender(s)—including demographic data, their criminal records, and their relationship to one another; the time and location of the incident precipitating the fatality; the circumstances, motive, and method of the fatal injury; and the security and

violence prevention activities in the school and community where the death occurred, before and after the fatal injury event. The revised data collection process eliminating the use of telephone interviews will reduce respondents' burden greatly.

All data are secured through the use of technical, physical, and administrative controls. Hard copies of data are kept under lock and key in secured offices, located in a secured facility that can be accessed only by presenting the appropriate credentials. Digital data are password protected and then stored (and backed up routinely) onto a secure Local Area Network that can only be accessed by individuals who have been appropriately authorized. Study data are reported in the aggregate, such that no individual case can be identified from the reports. There are no costs to the respondents other than their time. The total estimated annual burden hours are 17.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Law Enforcement Officer	Law Enforcement Case Confirmation Script .. Letter to Local Law Enforcement Officials	50 50	1 1	5/60 15/60

Jeffrey M. Zirger,

*Lead, Information Collection Review Office,
Office of Scientific Integrity, Office of Science,
Centers for Disease Control and Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, and the Determination of the Chief Operating Officer, CDC, pursuant to Public Law 92-463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as

patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—PS15-001SUPP, Positive Health Check Evaluation Trial.

Date: June 27, 2019.

Time: 10:00 a.m.–5:00 p.m., (EDT).

Place: Teleconference.

Agenda: To review and evaluate grant applications.

For Further Information Contact:

Gregory Anderson, M.S., M.P.H., Scientific Review Officer, CDC, 1600 Clifton Road NE, Mailstop E60, Atlanta, Georgia 30329, (404) 718-8833, gca5@cdc.gov.

The Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and

Prevention and the Agency for Toxic Substances and Disease Registry.

Sherri Berger,

Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2019-08929 Filed 5-1-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-1346]

Development of Antiviral Drugs for the Treatment of Adenoviral Infection in Immunocompromised Patients; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled “Development of Antiviral Drugs for the Treatment of Adenoviral Infection in

Immunocompromised Patients.” The purpose of the public workshop is to discuss the scientific and clinical trial design considerations for development of antiviral products to treat adenoviral infection.

DATES: The public workshop will be held on August 8, 2019, from 8:30 a.m. to 4:30 p.m. Submit either electronic or written comments on this public workshop by September 8, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 8, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time on September 8, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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-2019-N-1346 for “Development of Antiviral Drugs for the Treatment of Adenoviral Infection in Immunocompromised Patients.” Received comments, those filed in a timely manner (see **ADDRESSES**), 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: Lori Benner and/or Jessica Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6221, Silver Spring, MD 20993-0002, 301-796-1300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing a public workshop related to the development of antiviral drugs to treat adenoviral infection in immunocompromised patients. Discussions will focus on scientific and clinical trial design considerations and potential paths forward for antiviral drug development.

II. Topics for Discussion at the Public Workshop

Discussions are planned around the following topics:

- Trial design considerations (e.g., trial endpoints, trial populations, treatment strategies, risk/benefit considerations, ethical considerations, virologic testing considerations)
 - Diagnostic assay(s) considerations
- The Agency encourages healthcare providers, other U.S. Government Agencies, academic experts, industry, and other stakeholders to attend this public workshop.

III. Participating in the Public Workshop

Registration: Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register online by August 1, 2019, 11:59 p.m. Eastern Time. To register, please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone to <https://www.eventbrite.com/e/development-of-antiviral-drugs-for-the-treatment-of-adenoviral-infection-in->

immunocompromised-tickets-55714561754.

Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Jessica Barnes or Lori Benner (see **FOR FURTHER INFORMATION CONTACT**) no later than August 1, 2019.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by August 2, 2019. All requests to make oral presentations must be received by the close of registration on July 29, 2019. If selected for presentation, any presentation materials must be emailed to ONDPublicMTGSupport@fda.hhs.gov no later than August 5, 2019. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast at the following site: <https://collaboration.fda.gov/oapdavp080819>.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see

ADDRESSES). A link to the transcript will also be available on the internet at <https://www.fda.gov/Drugs/NewsEvents/ucm630653.htm>.

Dated: April 29, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-08993 Filed 5-1-19; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-0001]

Preparation for International Cooperation on Cosmetics Regulation Thirteenth Annual Meeting; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled "International Cooperation on Cosmetics Regulation (ICCR)—Preparation for ICCR-13 Meeting." The purpose of the public meeting is to invite public input on various topics pertaining to the regulation of cosmetics. We may use this input to help us prepare for the ICCR-13 meeting that will be held July 9 to 11, 2019, in Montreal, Canada.

DATES: The public meeting will be held on June 5, 2019, from 2 p.m. to 4 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr., Wiley Auditorium (first floor), College Park, MD 20740.

FOR FURTHER INFORMATION CONTACT: Jonathan Hicks, Office of Cosmetics and Colors, Food and Drug Administration, 5001 Campus Dr. (HFS-125), College Park, MD 20740, 240-402-1375, Jonathan.Hicks@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The intention of the ICCR multilateral framework is to pave the way for the removal of regulatory obstacles to international trade while maintaining global consumer protection. The purpose of the meeting is to invite public input on various topics pertaining to the regulation of cosmetics. We may use this input to

help us prepare for the ICCR-13 meeting that will be held July 9 to 11, 2019, in Montreal, Canada.

ICCR is a voluntary international group of cosmetics regulatory authorities from Brazil, Canada, the European Union, Japan, and the United States of America. These regulatory authority members will engage in constructive dialogue with their relevant cosmetics industry trade associations and public advocacy groups. Currently, the ICCR members are: The Brazilian Health Surveillance Agency; Health Canada; the European Commission Directorate-General for Internal Market, Industry, Entrepreneurship, and Small and Medium-sized Enterprises; the Ministry of Health, Labor, and Welfare of Japan; and FDA. All decisions are made by consensus and will be compatible with the laws, policies, rules, regulations, and directives of the respective administrations and governments. Members will implement and/or promote actions or documents within their own jurisdictions and seek convergence of regulatory policies and practices. Successful implementation will need input from stakeholders.

II. Topics for Discussion at the Public Meeting

We will make the agenda for the public meeting available on the internet at <https://www.fda.gov/Cosmetics/InternationalActivities/ICCR/default.htm>. Depending on the number of requests for oral presentations, we intend to have an agenda available by May 29, 2019.

III. Participating in the Public Meeting

Registration: To register for the public meeting, send registration information (including your name, title, affiliation, address, email, and telephone), to Jonathan Hicks by May 22, 2019. If you would like to listen to the meeting by phone, please submit a request for a dial-in number by May 22, 2019 (see **FOR FURTHER INFORMATION CONTACT**). If you need special accommodations due to a disability, please contact Jonathan Hicks by May 29, 2019.

Requests for Oral Presentations: If you wish to present, you should notify Jonathan Hicks by May 22, 2019, and submit a brief statement of the general nature of the presentation: What you wish to present, your name, title, affiliation, address, email, and telephone, and indicate the approximate amount of time needed to make your presentation. You may wish to present proposals for future ICCR agenda items, data, information, or views, in person or in writing, on issues pending at the