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Notice to Readers: Newly Licensed Smallpox Vaccine to Replace Old Smallpox Vaccine

CDC has begun distribution of a new-generation smallpox vaccine, ACAM2000TM (Acambis, Inc., Cambridge, Massachusetts), to civilian laboratory personnel, the military, and state public health preparedness programs. ACAM2000 is a live, vaccinia virus smallpox vaccine that was licensed for use in the United States by the Food and Drug Administration in August 2007 (1).^{*} ACAM2000 will be replacing Dryvax[®] smallpox vaccine (Wyeth Pharmaceuticals, Inc., Marietta, Pennsylvania) because of withdrawal of the Dryvax license. ACAM2000 is a live vaccinia virus derived from plaque purification cloning from Dryvax. The safety data available from the ACAM2000 clinical trials indicate a similar safety profile to Dryvax.

Wyeth intends to withdraw the Dryvax license and asks that all remaining quantities of vaccine held by civilian and military users be quarantined by February 29, 2008, for the purpose of destruction. This withdrawal is not necessitated by any safety, purity, or quality concerns with the product but rather is consistent with a contract agreement between CDC and Wyeth.[†] All lots of Dryvax vaccine will expire on February 29, 2008, and should not be used after that date.

All Dryvax vaccine should be destroyed on site. Vaccine vials can be 1) dropped into the hospital sharps container and autoclaved or 2) disposed of following the procedure for all other biohazard materials. In sites where medical waste is buried, soaking the medical waste in a 1:10 dilution of bleach for at least 10 minutes before disposal is advised. All programs that hold supplies of Dryvax vaccine must provide documentation of Dryvax vaccine destruction to the CDC Drug Service by March 31, 2008. These programs are advised to use the Dryvax vaccine destruction form.[§]

CDC will continue to provide ACAM2000 smallpox vaccine to protect responders as part of state public health preparedness programs (2) and civilian laboratory personnel who risk exposure to orthopoxviruses (3). Unlike Dryvax, ACAM2000 expires 18 months after release from the CDC Strategic National Stockpile. Requests for smallpox vaccine should be directed to the CDC Drug Service by e-mail (drugservice@cdc.gov) or telephone (404-639-3670).

References

1. Food and Drug Administration. Product approval information. Available at <http://www.fda.gov/cber/products/acam2000.htm>.
2. CDC. Recommendations for using smallpox vaccine in a pre-event vaccination program: supplemental recommendations of the Advisory Committee on Immunizations Practices (ACIP) and the Healthcare Infection Control Practices Advisory Committee (HICPAC). MMWR 2003;52 (Dispatch).

3. [CDC. Smallpox vaccine available for protection of at-risk laboratory workers. MMWR 1983;32:543--4.](#)

* ACAM2000 package insert and medication guide are available at <http://www.acambis.com/acam2000>.

† Additional information regarding the withdrawal is communicated in a letter, dated February 1, 2008, from Wyeth to the CDC Drug Service; the letter is available at http://emergency.cdc.gov/agent/smallpox/vaccination/pdf/ltr_cdc_010208_dryvax.pdf.

§ Available at http://emergency.cdc.gov/agent/smallpox/vaccination/pdf/dryvax_destruction_note_gen.pdf.

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Date last reviewed: 2/27/2008

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