

FOR FURTHER INFORMATION CONTACT:

Gloria J. Dunnavan, Center for Veterinary Medicine (HFV-230), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1166, e-mail: gloria.dunnavan@fda.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** dated April 8, 2004 (69 FR 18594), FDA announced the availability of a guidance for industry (#172) entitled "Use of Unapproved Hormone Implants in Veal Calves." This guidance outlined special measures to ensure the safety of veal in response to the identified illegal use of unapproved hormone implants in veal calves. The policy outlined in this guidance only applied to veal calves presented for slaughter prior to June 6, 2004. Therefore, the guidance is no longer relevant and is being withdrawn. Because there is no approved animal drug application providing for the use of these implants in veal calves, such use is illegal. Under section 512 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b), use of an unapproved new animal drug results in the drug being unsafe, and, therefore, the drugs are adulterated under section 501(a)(5) of the act (21 U.S.C. 351(a)(5)). In addition, food that bears or contains these drugs is adulterated under section 402(a)(2)(C)(ii) of the act (21 U.S.C. 342(a)(2)(C)(ii)).

Dated: July 9, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission of Childhood Vaccines Request for Nominations for Voting Members

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill three vacancies on the Advisory Commission on Childhood Vaccines (ACCV). The ACCV was established by Title XXI of the Public Health Service Act (the Act), as enacted by Public Law (Pub. L.) 99-660 and as subsequently amended, and advises the Secretary of Health and Human Services (the Secretary) on issues related to implementation of the

National Vaccine Injury Compensation Program (VICP).

DATES: The agency must receive nominations on or before August 16, 2004.

ADDRESSES: All nominations are to be submitted to the Acting Director, Division of Vaccine Injury Compensation (DVIC), Special Programs Bureau, HRSA, Parklawn Building, Room 16C-17, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Ms. Cheryl A. Lee, Principal Staff Liaison, Policy Analysis Branch, DVIC, at (301) 443-2124 or email: CLee@hrsa.gov.

SUPPLEMENTARY INFORMATION: Under the authorities that established the ACCV, the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463) and section 2119 of the Act, 42 U.S.C. 300aa-19, as added by Pub. L. 99-660 and amended, HRSA is requesting nominations for three voting members of the ACCV.

The ACCV advises the Secretary on the implementation of the VICP. The activities of the ACCV include: Recommending changes in the Vaccine Injury Table at its own initiative or as the result of the filing of a petition; advising the Secretary in implementing section 2127 regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; surveying Federal, State, and local programs and activities related to gathering information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 2125(b); advising the Secretary on the methods of obtaining, compiling, publishing, and using credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; and recommending to the Director of the National Vaccine Program that vaccine safety research be conducted on various vaccine injuries.

The ACCV consists of nine voting members appointed by the Secretary as follows: Three health professionals, who are not employees of the United States Government and have expertise in the health care of children, the epidemiology, etiology and prevention of childhood diseases, and the adverse reactions associated with vaccines, at least two shall be pediatricians; three members from the general public, at least two shall be legal representatives (parents or guardians) of children who have suffered a vaccine-related injury or death; and three attorneys, at least one shall be an attorney whose specialty includes representation of persons who

have suffered a vaccine-related injury or death, and one shall be an attorney whose specialty includes representation of vaccine manufacturers. In addition, the Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of the Food and Drug Administration (or the designees of such officials) serve as nonvoting ex officio members.

Specifically, HRSA is requesting nominations for three voting members of the ACCV representing: (1) A pediatrician, who has expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases; (2) an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death; and (3) a legal representative (parent or guardian) of a child who has suffered a vaccine-related injury or death. Nominees will be invited to serve a 3-year term beginning January 1, 2005, and ending December 31, 2007.

Interested persons may nominate one or more qualified persons for membership on the ACCV. Nominations shall state that the nominee is willing to serve as a member of the ACCV and appears to have no conflict of interest that would preclude the ACCV membership. Potential candidates will be asked to provide detailed information concerning consultancies, research grants, or contracts to permit evaluation of possible sources of conflicts of interest. A curriculum vitae or resume should be submitted with the nomination.

The Department of Health and Human Services has special interest in assuring that women, minority groups, and the physically disabled are adequately represented on advisory committees; and therefore, extends particular encouragement to nominations for appropriately qualified female, minority, or disabled candidates.

Dated: July 8, 2004.

Elizabeth M. Duke,
Administrator.

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