or becomes enjoined from marketing unapproved drugs may not resume marketing of unapproved single-ingredient oral colchicine based on FDA’s exercise of enforcement discretion as set forth in this notice.

Drug manufacturers and distributors should be aware that the agency is exercising its enforcement discretion as described previously only in regard to unapproved single-ingredient oral colchicine products that are marketed under an NDC number listed with the agency in full compliance with section 510 of the act before September 30, 2010. As previously stated, unapproved single-ingredient oral colchicine products that are currently marketed but not listed with the agency on the date of this notice must, as of the effective date of this notice, have approved applications before shipment in interstate commerce.

D. Discontinued Products

Some firms may have previously discontinued the manufacturing or distribution of products covered by this notice without removing them from the listing of their products under section 510(j) of the act. Other firms may discontinue manufacturing or marketing listed products in response to this notice. Firms that wish to notify the agency of product discontinuation should send a letter, signed by the firm’s chief executive officer, fully identifying the discontinued product(s), including the product NDC number(s), and stating that the product(s) has (have) been discontinued. The letter should be sent electronically to edrls@fda.hhs.gov. Firms should also update the listing of their products under section 510(j) of the act to reflect discontinuation of unapproved single-ingredient colchicine products. FDA plans to rely on its available information when we evaluate subsequent inspection, or other action, to determine whether to enforce the ban.

This notice is issued under the act (sections 502 (21 U.S.C. 352) and 505) and under authority delegated to the Deputy Commissioner, Office of Policy, Planning and Budget under section 1410.21 of the FDA Staff Manual Guide.

Dated: September 27, 2010.

Leslie Kux,
Acting Assistant Commissioner for Policy.

DEPARTMENT OF HOMELAND SECURITY

Critical Infrastructure Partnership Advisory Council (CIPAC)

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: Notice of CIPAC meeting.

SUMMARY: The CIPAC will meet on October 13, 2010 in Bethesda, MD. The meeting will be open to the public.

DATES: The CIPAC will meet Wednesday, October 13, 2010 from 8:30 a.m. to 12:30 p.m. Please note that the meeting may adjourn early if the committee has completed its business. For additional information, please consult the CIPAC Web site, http://www.dhs.gov/cipac, or contact the CIPAC Secretariat by phone at 703–235–3999 or by e-mail at CIPAC@dhs.gov.

FOR FURTHER INFORMATION CONTACT: Renee Murphy, Section Chief Partnership Programs, Partnership and Outreach Division, Office of Infrastructure Protection, National Protection and Programs Directorate, United States Department of Homeland Security, Mail Stop 0607, 245 Murray Lane, Washington, DC 20528–0607, telephone 703–235–3999 or by e-mail at CIPAC@dhs.gov.

RESPONSIBLE DHS OFFICIAL: Renee Murphy, Section Chief Partnership Programs, Partnership and Outreach Division, Office of Infrastructure Protection, National Protection and Programs Directorate, United States Department of Homeland Security, Mail Stop 0607, 245 Murray Lane, Washington, DC 20528–0607, telephone 703–235–3999 or by e-mail at CIPAC@dhs.gov.

SUPPLEMENTARY INFORMATION: CIPAC represents a partnership between the Federal Government and critical infrastructure owners and operators and provides a forum in which they can engage in a broad spectrum of activities to support and coordinate critical infrastructure protection.

The CIPAC will meet to discuss issues relevant to the protection of critical infrastructure. The October 13, 2010 meeting will include panel discussions between participating Sectors regarding Regionalization and Resilience and Information Sharing.

PROCEDURAL: While this meeting is open to the public, participation in the CIPAC deliberations is limited to committee members, DHS officials, and persons invited to attend the meeting for special presentations.

Information on Services for Individuals with Disabilities: For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the CIPAC Secretariat at 703–235–3999 as soon as possible.


Renee Murphy,
Alternate Designated Federal Officer for the CIPAC.