

Comisión Nacional del Mercado de Valores
Att. Sr. D. Rodrigo Buenaventura
C/ Miguel Ángel 11, 1º
28010 Madrid

Madrid, 25 de Junio de 2009

Muy Sres. Nuestros:

Por la presente les informamos que la FDA ha publicado que el próximo día 15 de julio de 2009 tendrá lugar una reunión pública de su Oncologic Drugs Advisory Comité (ODAC) en la que entre otras materias tratará sobre la solicitud de autorización de comercialización de YONDELIS (trabectedin) en combinación con DOXIL, para el tratamiento de pacientes con cáncer de ovario en recaída, solicitud que fue presentada por Centocor Ortho Biotech Products, L.P. el pasado mes de noviembre de 2008. Adjunto a la presente les acompañamos copia de dicha convocatoria que ha sido publicada en la página web de la FDA (www.federalregister.gov/OFRUpload/OFRData/2009-13372_PI.pdf). Todo lo anterior a fin que sea registrada como **OTRAS COMUNICACIONES**.

Sin otro particular les saluda atentamente,

Sebastián Cuenca Miranda
Secretario del Consejo de Administración

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA2009N0664]

Oncologic Drugs Advisory Committee; Notice of Meeting

AGENCY:

Food and Drug Administration, HHS.

ACTION:

Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Oncologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on July 15, 2009, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy, Gaithersburg, MD. The hotel telephone number is 3019778900.

Contact Person: Nicole Vesely, Center for Drug Evaluation and Research (HFD21), Food and Drug Administration, 5600 Fishers Lane, (for express delivery, 5630 Fishers Lane, rm. 1093) Rockville, MD 20857, 3018276793, FAX: 3018276776, e-mail: nicole.vesely@fda.hhs.gov, or FDA Advisory Committee Information Line, 18007418138 (3014430572 in the Washington, DC area), code 3014512542. Please call the Information Line for up-to-date information on this meeting. A notice in the Federal Register about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss: (1) new drug application (NDA) 022447, proposed trade name YONDELIS (trabectedin) powder, for concentrate for solution for intravenous infusion, Centocor Ortho Biotech Products, L.P., proposed indication in combination with DOXIL (doxorubicin HCl liposome injection), for the treatment of patients with relapsed ovarian cancer; and (2) supplemental new drug application (sNDA) 050718/S039, DOXIL (doxorubicin HCl liposome injection), for intravenous infusion, Centocor Ortho Biotech Products, L.P., proposed indication in combination with docetaxel for the treatment of patients with locally advanced or metastatic breast cancer who have received prior anthracycline treatment.

FDA intends to make background material available to the public no later than 2

business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/ohrms/dockets/ac/acmenu.htm>, click on the year 2009 and scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 30, 2009. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m., and 3:30 p.m. to 4 p.m. Those desiring to make formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before June 22, 2009. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by June 23, 2009.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Nicole Vesely at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/oc/advisory/default.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: May 29, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

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