



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0621]

Final Decision on Withdrawal of Breast Cancer Indication for AVASTIN (Bevacizumab)

Following Public Hearing; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the final decision withdrawing approval of the breast cancer indication for AVASTIN (Bevacizumab). The Commissioner of Food and Drugs (the Commissioner) issued the decision following a June 2011 public hearing on a proposal to withdraw the approval.

DATES: Withdrawal of AVASTIN's breast cancer indication was effective November 18, 2011.

ADDRESSES: Submit written requests for single copies of the decision to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. The final decision, hearing transcript, and other documents may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1601, Rockville, MD 20852. See the SUPPLEMENTARY INFORMATION section for electronic access to the decision and related documents.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

On February 22, 2008, FDA's Center for Drug Evaluation and Research (CDER) approved a supplemental biologics license application (sBLA 125085/91) submitted by Genentech, Inc. (Genentech), for the use of AVASTIN in combination with paclitaxel for patients who have not received chemotherapy for treatment of HER2-negative metastatic breast cancer (MBC). This approval was issued under the Agency's accelerated approval regulations for biological products, 21 CFR part 601, subpart E. Consistent with those regulations, the approval was subject to the requirement that the product be studied further to verify and describe its clinical benefit. On November 16, 2009, Genentech submitted the results of two clinical trials intended to satisfy this requirement. CDER determined that these trials failed to verify AVASTIN's clinical benefit in the treatment of MBC and on December 16, 2010, issued a notice of opportunity for a hearing to Genentech proposing to withdraw approval of AVASTIN's MBC indication. Genentech submitted a hearing request dated December 23, 2010, followed by a submission of data and information on which it would rely at a hearing. The Agency granted Genentech's hearing request and published a notice of hearing on May 11, 2011 (76 FR 27332). The hearing was held on June 28 and 29, 2011. Following the hearing, on November 18, 2011, the Commissioner issued a final decision withdrawing approval of AVASTIN's MBC indication.

II. Electronic Access

Persons with access to the Internet may obtain the final decision at <http://www.fda.gov/downloads/NewsEvents/Newsroom/UCM280546.pdf>. The final decision, a transcript of the hearing, and other documents pertaining to the withdrawal of Avastin's MBC indication are available at <http://www.regulations.gov> under the docket number found in brackets in the heading of this document.

Dated: February 21, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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