



European Medicines Agency
Press office

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PRESS RELEASE

CIS bio international withdraw their application for SCINTIMUN

The European Medicines Agency has been formally notified by CIS bio international S.A. of their decision to withdraw their application for a centralised marketing authorisation for the medicinal product SCINTIMUN (besilesomab) 1 mg, kit for radiopharmaceutical preparation.

CIS bio international submitted an application for marketing authorisation for SCINTIMUN to the EMEA on 3 February 2005. SCINTIMUN is a radiopharmaceutical for use in molecular imaging. The indications applied for were:

- Scintigraphic imaging for determining the location of infectious/inflammatory lesions;
- Scintigraphic imaging of bone marrow involvement (detection and extent of carcinoma metastasis, as cold spots).

Following review of the data submitted, the Committee for Medicinal Products for Human Use (CHMP) requested the company to submit additional data. In their official withdrawal letter, the company stated that due to the time needed to complete complementary studies, they were not able to respond to the Committee's request within the procedural timeframe.

In the European Union this product has already been authorised in the Czech Republic, Hungary and Sweden, where the company intends to continue its supply.

More information about SCINTIMUN and the current state of the scientific assessment at the time of withdrawal will be made available in a question and answer document. This document, together with the withdrawal letter from the company, will be published on the EMEA website, after the next meeting of the Committee for Medicinal Products for Human Use (CHMP) on 29 May – 1 June 2006.

--ENDS--

NOTES

1. The legal basis for the publication of this withdrawal are Articles 11 and 80 of Regulation (EC) No 726/2004.
2. Withdrawal of an application does not prejudice the possibility of a company to make a new application at a later stage.
3. This press release, together with other information about the work of the EMEA, may be found on the EMEA website: <http://www.emea.eu.int>

Media enquiries only to:

Martin Harvey Allchurch or Monika Benstetter

Tel: (44-20) 74 18 84 27, E-mail: press@emea.eu.int