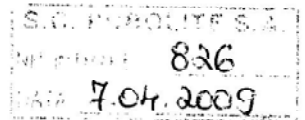




DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

CENTER FOR DRUG EVALUATION AND RESEARCH



Division of Manufacturing and Product Quality  
International Compliance Team  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993

TELEPHONE: (301) 796-3194  
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April 1, 2009

Mr. Satish Bapat  
General Manager, Purolite S.R.L.  
Str. Aleea Uzinei Nr. 11  
505700 Victoria  
Judetal Brasov, Romania

Dear Mr. Bapat:

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your active pharmaceutical ingredient manufacturing facility in Judetal Brasov, Romania on February 2-5, 2009 by FDA Investigator Laurie B. Frazier. Based on the inspection, we are classifying your facility as acceptable. It remains your responsibility to assure continued compliance with current good manufacturing practices. This letter is not intended as an endorsement or certification of the facility.

We note that this establishment is not registered with FDA as required by 21 CFR 207.40. Information on how to register is available at [http://www.fda.gov/cder/drls/registration\\_listing.htm](http://www.fda.gov/cder/drls/registration_listing.htm)

Additionally, we enclose a copy of the establishment inspection report (EIR). Releasing this EIR to you is part of FDA's effort to make its regulatory process and activities more transparent to the regulated industry. It is being provided to you for information purposes only and may reflect some redactions made by the Agency in accordance with the FOIA and C.F.R. Part 20. Copies provided to other requestors may have additional redactions of trade secret and confidential commercial information.

If you have any questions concerning this letter, you may contact me at the above address or telephone numbers.

Sincerely,

Elizabeth L. Johnson  
Compliance Officer  
International Compliance Team

Enclosure: