GRAYCARY
1625 Massachusetts Avenue NW, Suite 300
Washington, DC 20036-2247
drosen@graycary.com
www.graycary.com
O] 202-238-7749
F] 202-238-7701

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VIA EMAIL, FACSIMILE AND US MAIL

Dockets Management Branch, HFA 305
Food and Drug Administration
5630 Fishers Lane, Room 1031
Rockville, MD 20852

Re: Docket 77N-0094

Proposed Amendment of the OTC Tentative Final Monograph for Internal Analgesic, Antipyretic and Anti-rheumatic Drug Products for Over-The-Counter Human Use

Response to Comments Alleging that Foreign Sources of Ibuprofen Active Pharmaceutical Ingredients and Finished Dosage Forms Contain Unsafe Levels of Lead and/or Chromium; and

Request that the Petition to Amend the OTC Monograph be Denied as it is Not Necessary and Will Not Offer Any Further Benefit to the Public Health

Dear Sir/Madam:

I am writing on behalf of our clients, Reddy-Cheminor and Dr. Reddy's Laboratories to refute allegations made by the Albemarle Corporation on October 24, 2002 and BASF Corporation November 15, 2002 regarding the quality of certain foreign sources of Ibuprofen active pharmaceutical ingredient ("API") and Ibuprofen finished dosage forms. In addition, I am providing comments on behalf of Reddy-Cheminor and Dr. Reddy's Laboratories expressing the view that the Petition to amend the OTC Tentative Final Monograph for Internal Analgesic, Antipyretic and Anti-rheumatic Drug Products for Over-The-Counter Human Use to include Ibuprofen should be denied as it is not necessary to afford the public access to high quality, therapeutically equivalent and less costly generic versions of Ibuprofen and will not offer any further benefit to the public health. These issues are discussed below.

Reddy-Cheminor and Dr. Reddy's Laboratories Ibuprofen Products Meet The Highest Standard of Identity Strength Quality and Purity

Reddy-Cheminor produces significant quantities of the Ibuprofen API and supplies multiple currently approved ANDA holders with Ibuprofen, including Dr. Reddy's Laboratories. Reddy-Cheminor holds a current Drug Master File for Ibuprofen API and has employed tests and specifications for its API that have been determined to be acceptable by FDA chemistry reviewers and which Reddy-Cheminor consistently meets on a lot to lot basis. Moreover, Reddy-Cheminor's Ibuprofen API has been tested by multiple holders of approved ANDAs, including Dr. Reddy's and both the API as well as the Ibuprofen finished dosage forms meet tests and specifications on a lot to lot basis found acceptable by FDA reviewers.

Notwithstanding, to address allegations set forth by Albemarle and BASF, Reddy-Cheminor and Dr. Reddy's Laboratories provided samples of numerous lots of Ibuprofen API and finished dosage forms to an independent contract analytical laboratory (in compliance with applicable current good manufacturing practices and good laboratory practices) for trace element analysis. Twenty six different lots of Ibuprofen API manufactured by Reddy-Cheminor were tested and no lead, chromium or nickel were detected at the limits of detection by ICP-MS analysis. Five lots of finished Ibuprofen Tablets manufactured by Dr. Reddy's Laboratories were also tested (duplicate samples were analyzed) and no lead, chromium or nickel were detected at the limits of detection by ICP-MS analysis. The actual data results are deemed to be confidential and therefore are not being submitted to the docket. Notwithstanding, should Agency scientific staff wish to review the test data, please contact me to arrange a meeting and I will bring a copy of the data for Agency staff to review.

Reddy-Cheminor and Dr. Reddy's Laboratories are committed to manufacturing products in conformance with current good manufacturing practices that meet the highest standards of identity, strength, quality and purity. Their Ibuprofen products, both API and finished dosage forms, meet the FDA approved tests and specifications and do not contain levels of lead, chromium or nickel at the limits of detection by ICP-MS analysis.

The Petition to amend the OTC Tentative Final Monograph for Internal Analgesic, Antipyretic and Anti-rheumatic Drug Products for Over-The-Counter Human Use to include Ibuprofen Should be Denied

The is no need whatsoever to the Petition to amend the OTC Tentative Final Monograph for Internal Analgesic, Antipyretic and Anti-rheumatic Drug Products for Over-The-Counter Human Use to include Ibuprofen. The public currently has access to numerous high quality, therapeutically equivalent and less costly generic versions of Ibuprofen. Ibuprofen is a drug with a potential bioequivalence problem and currently to be marketed in the United States, requires the submission and approval of an abbreviated

new drug application which must include, among other items, a comparative *in vivo* bioequivalence study and *in vitro* dissolution study to establish that the generic product is bioequivalent to the reference listed drug. These requirements, among others, serve to ensure that generic products can be expected to provide the same therapeutic benefit as their brand name counterparts. The American public is entitled to generic products that meet the highest standards. The current ANDA approval requirements for marketing Ibuprofen has helped ensure that the public has access to the highest quality, therapeutically equivalent less expensive generic versions of Ibuprofen. There are many approved ANDAs for Ibuprofen. There is no need to amend the OTC monograph to permit access to Ibuprofen and the Citizen Petition should be denied.

On behalf of Reddy-Cheminor and Dr. Reddy's Laboratories, I want to thank the Agency for considering these comments. Please contact me to arrange a meeting should Agency scientific staff wish to review the test data. If you have any questions or need any further information, please call me at (202) 238-7749.

Sincerely yours,

David L. Rosen, R.Ph., J.D.

cc: Mr. Cameron Reid
Reddy-Cheminor
Dr. Reddy's Laboratories