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Via Electronic Filing And First Class Mail

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 2004P-0171/CP & 2003P-0176/CP

Dear Sir or Madam:

On behalf of Novartis Pharmaceuticals Corporation ("Novartis"), I am writing in reference to the submission dated July 12, 2005 by Robert A. Long, Jr., of Covington & Burling, who states that "[t]he Pharmaceutical Research and Manufacturers of America ("PhRMA") ha[d] asked [him] to analyze" various legal questions.

Novartis believes that Mr. Long's paper is fundamentally flawed in its premises – on the science and FDA regulatory review process. The faulty premise that underlies Mr. Long's entire argument is that a manufacturer of a follow-on protein product ("FOPP") and/or FDA *always* must rely on at least some confidential information of the innovator held by FDA. Hence, he concludes that a FOPP filing and or approval necessarily will trigger a per se "taking" in all cases. This is not true. An application for a FOPP can be prepared, submitted to, and reviewed by FDA's expert scientists without any specific reference to any of the trade secret information of the innovator sponsor.

Consistent with Novartis' support for strong IP protection, Novartis agrees that unauthorized use or disclosure of trade secrets or confidential commercial information without compensation could result in an unconstitutional taking. To the extent Mr. Long's external opinion purports to go further, Novartis disagrees with his submission.

Respectfully submitted,

D.P. Watson

Dorothy P. Watson