DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W. Scott Harkonen
125 Montalvo Ave.
San Francisco, CA 94116-1928

01-10-2012

PROPOSAL TO DEBAR
NOTICE OF OPPORTUNITY FOR HEARING
DOCKET No. FDA-2011-N-0758

Dear Dr. Harkonen:

This letter is to inform you that the Food and Drug Administration (FDA) is proposing to issue an order permanently debarring you from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this proposal on a finding that you were convicted of a felony under Federal law for conduct relating to the regulation of a drug product under the Federal Food, Drug, and Cosmetic Act (the Act). This letter also offers you an opportunity to request a hearing on this proposal.

Conduct Related to Conviction

On September 29, 2009, a jury found you guilty of one count of wire fraud, in violation of 18 U.S.C. § 1343. On April 13, 2011, judgment was entered against you in the United States District Court for the Northern District of California. The underlying facts supporting this conviction are as follows.

You were the Chief Executive Officer of InterMune Inc. (InterMune) from February 1998 through at least June 30, 2003. In addition, you were a member of InterMune's Board of Directors from February 1998 through September 2003 and you directed all aspects of InterMune's operations, including, but not limited to, research, marketing, and investor relations. You were also a medical doctor licensed to practice medicine in California.

InterMune, a California-based pharmaceutical company, developed, marketed and sold drugs for lung and liver diseases. One of the drugs that InterMune sold was called "interferon gamma-1b" and was marketed under the brand name of "Actimmune." By 2000, when InterMune purchased the rights to Actimmune, Actimmune had only been approved by the Food and Drug Administration ("FDA") for the treatment of two very rare conditions: chronic granulomatous disease and severe, malignant osteopetrosis.

In 1999, a small Austrian clinical trial showed that Actimmune might be a promising treatment for another disease, idiopathic pulmonary fibrosis ("IPF"). In response to the Austrian study, InterMune launched its own, much more ambitious study of Actimmune's efficacy in treating IPF. The study, known as the (b) (4) was designed primarily to test whether

patients being treated with Actimmune were more or less likely to experience "progression free survival time" — the time elapsed between treatment initiation and disease progression or death.

At the same time, InterMune marketed Actimmune as an off-label treatment for idiopathic pulmonary fibrosis (IPF), a use for which it had not been approved by FDA. At your direction, InterMune hired and grew a sales force to promote the off-label use of Actimmune as a treatment for IPF. Since Actimmune was not approved for the treatment of IPF at this time, its promotion by InterMune for such treatment was contrary to law.

In mid-August 2002, InterMune was provided with the results from (b) (4). On August 28, 2002, InterMune issued a press release, claiming, among other things, that the data from the study "[d]emonstrat[ed a] survival benefit of Actimmune in IPF" and that Actimmune "Reduces Mortality by 70% in Patients with Mild to Moderate Disease."

In fact, the (b) (4) study showed no efficacy with respect to its primary endpoint, progression-free survival time. Furthermore, the study also showed no statistically valid result for any one of its ten secondary endpoints. Only a post-hoc, subgroup analysis (a mode of analysis that is known to be of little value beyond generating hypotheses for further investigation) yielded a statistically significant result among those patients with mild to moderate impairment of lung function.

Despite these results, your press release characterized the clinical trial results as indicating that (b) (4) was a success and that Actimmune may extend the lives of patients suffering from IPF. The press release accorded statistical significance to (b) (4) results, and efficacy to Actimmune without any adjustment for context, including for secondary endpoints and post-hoc analyses.

Trial evidence overwhelmingly established that prior to August 28, 2002, you had been told by multiple sources that (b) (4) had missed its primary endpoint, progression-free survival time, as well as all ten secondary endpoints, including survival time. More importantly, at least two individuals informed you that the post-hoc, subgroup analyses on which your press release depended were interesting findings, but unreliable and inconclusive.

Knowing that the press release made false or misleading claims about Actimmune and (b) (4) results, you hid the draft press release from everyone at InterMune who had enough scientific knowledge to know that the statements in the press release were false or misleading representations. Your motivation for putting out the false or misleading press release was to illegally increase the sales of Actimmune.

FDA's Finding

Section 306(a)(2)(B) of the Act (21 U.S.C. § 335a(a)(2)(B)) requires debarment of an individual if FDA finds that the individual has been convicted of a felony under Federal law for conduct relating to the regulation of any drug product under the Act. As described in detail above, you committed wire fraud by illegally portraying Actimmune as effective in reducing the mortality of IPF patients in order to induce doctors and patients to use Actimmune as a treatment for an indication for which it had not been approved by FDA. Given that it is a violation of the Act for sponsors to promote a drug for an indication for which it has not been approved by FDA, FDA finds that that your federal felony conviction relates to the regulation of a drug product under the Act.

Section 306(c)(2)(A)(ii) of the Act (21 U.S.C. § 335a(c)(2)(A)(ii)) requires that your debarment be permanent.

Proposed Action and Notice of Opportunity for Hearing

Based on the findings discussed above, FDA proposes to issue an order under section 306(a)(2)(B) of the Act (21 U.S.C. § 335a(a)(2)(B)) permanently debarring you from providing services in any capacity to a person having an approved or pending drug product application.

In accordance with section 306 of the Act and 21 CFR part 12, you are hereby given an opportunity to request a hearing to show why you should not be debarred as proposed in this letter.

If you decide to seek a hearing, you must file the following: (1) on or before 30 days from the date of receipt of this letter, a written notice of appearance and request for hearing; and (2) on or before 60 days from the date of receipt of this letter, the information on which you rely to justify a hearing.

The procedures and requirements governing this notice of opportunity for hearing, a notice of appearance and request for a hearing, information and analyses to justify a hearing, and a grant or denial of a hearing are contained in 21 CFR part 12 and section 306(i) of the Act (21 U.S.C. § 335a(i)).

Your failure to file a timely written notice of appearance and request for hearing constitutes an election by you not to use the opportunity for a hearing concerning your debarment and a waiver of any contentions concerning this action. If you do not request a hearing in the manner prescribed by the regulations, FDA will not hold a hearing and will issue a final debarment order as proposed in this letter.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. A hearing will be denied if the data and information you submit, even if accurate, are insufficient to justify the factual determination urged. If it conclusively appears from the face of the information and factual analyses in your request for a hearing that there is no genuine and substantial issue of fact that precludes the order of debarment, the Commissioner of Food and Drugs will deny your request for a hearing and enter a final order of debarment.

You should understand that the facts underlying your conviction are not at issue in this proceeding. The only material issue is whether you were convicted as alleged in this notice and, if so, whether, as a matter of law, this conviction permits your debarment under section 306(a)(2)(B) of the Act (21 U.S.C. § 335a(a)(2)(B)) as proposed in this letter.

Your request for a hearing, including any information or factual analyses relied on to justify a hearing, must be identified with Docket No. FDA-2011-N-0758 and sent to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. You must file four copies of all submissions pursuant to this notice of opportunity for hearing. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under section 306 of the Act (21 U.S.C. § 335a) and under authority delegated to the Acting Director, Office of Enforcement within the Food and Drug Administration.

Sincerely,

Armando Zamora
Acting Director,
Office of Enforcement
Office of Regulatory Affairs

cc:
HF-22/Matthew Warren
HFC-130/ Michael Rogers
HFC-300/ Jeffrey Ebersole
GCF-1/ Seth Ray
HFD-1/Dr. John Jenkins
HFD-300/ Ilisa Bernstein
HFD-300/Douglas Stearn
HFD-300/Harry Schwirck
HFD-003/Keith Webber
HFC-2/ Michael Verdi

HFD-45/Leslie Ball
HFD-45/Constance Lewin
HFD-45/Sherbert Samuels
HFV-200/Daniel G. McChesney

HFC-230/Debarment File
HFC-230/CF
HFM-100 (CBER)
HFC-200/CF