KEVIN V. RYAN (CSBN 118321)
United States Attorney

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

CR 08 0707

UNITED STATES OF AMERICA, Plaintiff, v. INTERMUNE, INC., Defendant.	No. VIOLATION: 21 U.S.C. §§ 331(k), 333(a)(2) - Misbranding SAN FRANCISCO VENUE

INFORMATION

The United States Attorney charges:

INTRODUCTION

At all times material and pertinent to this Information:

1. The United States Food and Drug Administration ("FDA") was the federal agency within the United States Department of Health and Human Services charged with enforcing the Federal Food, Drug, and Cosmetic Act ("FDCA" or "the Act") to protect the health and safety of the American public. Under the Act, a drug was misbranded if its labeling did not bear adequate

directions for use to permit a layperson to administer the drug safely for each of its intended uses. 21 U.S.C. § 352(f)(1); 21 C.F.R. § 201.5.

2. A "prescription drug" was a drug which, "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measure necessary for its use, [was] not safe for use except under the supervision of a practitioner licensed by law to administer such drug" or a drug which was "limited by an approved [new drug application] to use under the supervision of a practitioner licensed by law to administer such drug." 21 U.S.C. § 353(b)(1). A prescription drug, by definition, could not bear adequate directions for use by a layperson.

3. If a prescription drug did not bear adequate directions for use for all of its intended uses, and if it was not subject to an exemption from the requirement that it bear adequate directions for use for all of its intended uses, the drug was misbranded under the FDCA. 21 U.S.C. § 352(f)(1); 21 C.F.R. § 201.115.

4. The FDCA prohibited the doing of any act with respect to a drug, if the act was done while the drug was held for sale after shipment in interstate commerce and resulted in the drug being misbranded. 21 U.S.C. § 331(k).

STATEMENT OF FACTS

5. Defendant, InterMune, Inc., was a biopharmaceutical company engaged in developing and commercializing therapies in pulmonology and hepatology, with its principal place of business located in Brisbane, California.

6. The FDA approved the use of the drug Actimmune® (interferon gamma-1b) for the treatment of chronic granulomatous disease and severe, malignant osteopetrosis.

7. Actimmune® was a "drug" within the meaning of 21 U.S.C. § 321(g)(1)(B) and (C), and it was a "prescription drug" within the meaning of 21 U.S.C. § 353(b). Actimmune® was not exempt under 21 C.F.R. § 201.115 from the requirement that it bear adequate directions for use for all of its intended uses.

8. Defendant InterMune contracted with a specialty pharmacy located in Florida to distribute Actimmune® to patients located in the Northern District of California and elsewhere.

9. From at least August 2002 until at least January 2003, in the Northern District of

California and elsewhere, Defendant InterMune promoted Actimmune® for the treatment of idiopathic pulmonary fibrosis (IPF), a new intended use for Actimmune®, for which InterMune did not have an approved New Drug Application or effective Investigational New Drug application.

COUNT ONE

From in or about August 2002 until in or about January 2003, within the Northern District of California and elsewhere, the defendant INTERMUNE, INC., with the intent to defraud and mislead, promoted the drug Actimmune® for the treatment of idiopathic pulmonary fibrosis, a condition for which it was not approved by FDA, while the drug was held for sale after shipment in interstate commerce, which resulted in the drug being misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that its labeling did not bear adequate directions for use, all in violation of 21 U.S.C. §§ 331(k) and 333(a)(2).

DATED: October 24, 2006

United States Attorney
KEVIN V. RYAN

KEVIN V. RYAN
United States Attorney

(Approved as to form: _____
AUSA IOANA PETROU

CERTIFICATE OF SERVICE

The undersigned hereby certifies that he is an employee of the office of the United States Attorney, Northern District of California and is a person of such age and discretion to be competent to serve papers. The undersigned certifies that he caused copies of

INFORMATION

in the case of **United States v. Intermune, Inc., No. TBD**
to be served on the parties in this action, addressed as follows which are the last known addresses and fax numbers:

Barbara Hoffman
Covington & Burling LLP
1330 Avenue of the Americas
New York, New York 10019
212-841-1143
Fax: 646-441-9143
bhoffman@cov.com

____(By Personal Service), I caused such envelope to be delivered by hand to the person or offices of each addressee(s) above.

____ (By Facsimile), I caused each such document to be sent by Facsimile to the person or offices of each addressee(s) above.

____ (By Mail), I caused each such envelope, with postage thereon fully prepaid, to be placed in the United States mail at San Francisco, California.

__X__(By Fed Ex), I caused each such envelope to be delivered by FED EX to the address listed above.

I declare under penalty of perjury that the foregoing is true and correct.

October 26, 2006

TYLE L. DOERR
United States Attorney's Office