Metro Washington Field Office
Sentencing/Convictions
May 2, 2005, Luigi RATTI, former President and Chief Executive Officer of BIOCHIMICA OPOS sentenced in the USA to one (1) month and two (2) days incarceration; twelve (12) months of home detention; pay a criminal fine of $16,481,000; and forfeit $300,000 to the United States government.
www.eddi-inc.com/news8.cfm

Foreign drug firm pleads guilty to felony charges - Investigator's Reports - Roussel Uclaf S.A. pleads guilty to fraud on behalf of Biochimica Opos Sentenced to Pay U.S. $33 Million
Rousell Uclaf pled guilty and was sentenced under a two count information charging the company with conspiracy and the introduction of adulterated drugs in interstate commerce with the intent to defraud or mislead, in violation of the Federal Food, Drug, and Cosmetic Act.
This case represents the first time that a foreign corporation has been criminally punished based upon defrauding the FDA concerning a drug product which it manufactured wholly outside the United States but marketed to the American public. It is also among the largest monetary penalties ever imposed in a criminal pharmaceutical prosecution.
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The case against BIOCHIMICA OPOS (OPOS) was initiated in 1997 based on a referral from the Office of Compliance, Center for Drug Evaluation and Research (CDER). Eli Lilly had alleged to CDER that OPOS, an Italian manufacturer of bulk active pharmaceutical ingredients, had falsified FDA submissions related to the locations and methods they used to manufacture cefaclor and other drug products. CDER directed that an inspection be conducted on-site at OPOS' facility in Agrate Brianza, Italy, where evidence of falsified production records was discovered.

The ensuing investigation uncovered three specific crimes committed during OPOS's manufacture of cefaclor. First, the company subcontracted out the manufacture of one intermediate ingredient to Archimica, which was proper, but Archimica then re-subcontracted that step to an unapproved firm in Iasi, Romania. Second, OPOS subcontracted out the manufacture of two additional intermediates to Archimica which it was not allowed to do under its own drug master file. Finally, OPOS substituted a required chemical in the processing of cefaclor with a different, unapproved chemical. The investigation revealed Luigi RATTI controlled both OPOS and Archimica and would make 5% of the profits realized by OPOS.

On October 19, 2001, Aventis Pharmaceuticals, Inc., parent company of Roussel-Uclaf and BIOCHIMICA OPOS, was convicted of violating Title 18, U.S.C. § 371 - Conspiracy and Title 21, U.S.C. § 331 (a) - Distribution of Adulterated Drugs. The company was sentenced to pay a criminal fine of $23,193,660 and to voluntarily forfeit $10,000,000 to the United States.

The investigation into the people who were behind the conspiracy continued. The investigation revealed that RATTI orchestrated the creation and maintenance of false records that were used to

mislead the FDA during its inspections of OPOS. The documents stated the drug was manufactured in accordance with the company's FDA submissions but concealed the fact that elements of the manufacture had been subcontracted out to another RATTI-controlled corporation and a Romanian firm that were not authorized to conduct those steps. Those documents also concealed the fact that an unapproved chemical was used in the process of making cefaclor.

On July 16, 2003, RATTI, former President and Chief Executive Officer of BIOCHIMICA OPOS, was named in a sealed indictment. The indictment listed twelve charges, including shipment of adulterated drugs in interstate commerce, making false statements, wire fraud and conspiracy. A warrant was issued for his arrest, but RATTI remained an Italian citizen residing in Switzerland.

On March 30, 2004, RATTI, attempted to enter the United States at the Miami International Airport. He was unaware of the arrest warrant and was arrested and placed in the custody of the United States Marshal's Service. On April 1, 2004, RATTI was detained without bond and extradited to the District of Maryland.

Eventually, on May 2, 2005, RATTI was convicted of violating Title 21, U.S.C. § 331 (d) and 333 (a) (2) - Introduction or Delivery into Interstate Commerce an Unapproved Drug. RATTI was sentenced to one (1) month and two (2) days incarceration; twelve (12) months of home detention; pay a criminal fine of $16,481,000; and forfeit $300,000 to the United States government.

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Foreign drug firm pleads guilty to felony charges - Investigator's Reports - Roussel Uclaf S.A. pleads guilty to fraud on behalf of Biochimica Opos S.p.A - Brief Article

FDA Consumer, Jan-Feb, 2002 by Carol Lewis
A French pharmaceutical company has been fined $33 million for deliberately failing to disclose to Food and Drug Administration officials all of the locations where the antibiotic cefaclor was being manufactured. The monetary penalty is one of the largest ever imposed in a criminal pharmaceutical prosecution.

Paris-based Roussel Uclaf S.A. was ordered to pay the fine after pleading guilty on behalf of its Italian subsidiary company, Biochimica Opos S.p.A., to felony charges of conspiracy and introducing adulterated drugs into interstate commerce with the intent to defraud or mislead. Cefaclor, approved to treat various infections, was being marketed to American consumers, but was manufactured outside the United States at facilities not disclosed to the FDA. The purpose of the illegal scheme was to increase sales of cefaclor in the United States, according to FDA special agents.

U.S. District Judge Peter J. Messitte in Greenbelt, Md., handed down the fine in October 2001. The case represents the first time that a foreign corporation has been criminally punished for defrauding the FDA concerning an approved drug product manufactured outside the United States and marketed to the American public.

French Drug Firm Pleads Guilty to Felony: Sentenced to Pay U.S. $33 Million
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Greenbelt- Thomas M. DiBaggio, United States Attorney for the District of Maryland, Assistant Attorney General Robert D. McCallum, Jr., of the Department of Justice's Civil Division, and Bernard A. Schwetz, Acting Commissioner of the Food and Drug Administration announced today that a French corporation, Roussel Uclaf S.A., pleaded guilty to felony charges of conspiracy and defrauding the Food and Drug Administration. U.S. District Judge Peter J. Messitte then sentenced the company to pay criminal and civil penalties of over $33,000,000 pursuant to a plea agreement between Aventis, Pharma A.G.(the successor corporation to Roussel Uclaf) and the United States Attorney's Office for the District of Maryland and Department of Justice.

This case represents the first time that a foreign corporation has been criminally punished based upon defrauding the FDA concerning a drug product which it manufactured wholly outside the United States but marketed to the American public. It is also among the largest monetary penalties ever imposed in a criminal pharmaceutical prosecution.

Rousell Uclaf pled guilty and was sentenced under a two count information charging the company with conspiracy and the introduction of adulterated drugs in interstate commerce with the intent to defraud or mislead, in violation of the Federal Food, Drug, and Cosmetic Act.

According to the statement of facts to which a Rousel Uclaf representative admitted, the case involved Roussel Uclaf's manufacture of the drug cefaclor in 1995 and 1996 through an Italian company, Biochimica Opos S.p.A., which was a wholly-owned subsidiary of Roussel Uclaf. Cefaclor is an antibiotic used to treat various infections, including upper and lower respiratory infections, pharingytis, tonsillitis, urinary tract infections, and skin infections. Although manufactured wholly outside the United States, Roussel Corporation, another wholly-owned subsidiary of Roussel Uclaf, distributed cefaclor and other drug products manufactured by Roussel Uclaf and Biochimica Opos in the United States.

Since that time, through a series of corporate combinations, Roussel Uclaf has become part of Aventis S.A. and its pharmaceutical arm, Aventis Pharma AG. Aventis Pharma, located in Frankfurt, Germany, is now one of the largest pharmaceutical companies in the world.

According to facts set forth in the plea agreement, between April 1995 and September 1996, various individuals, including authorized agents of Roussel Uclaf, willfully sought to mislead the Food and Drug Administration (FDA) about where and how cefaclor was being manufactured. The purpose of the illegal scheme was to increase the amount of cefaclor available for sale by Roussel Corporation in the United States. Agents of Roussel Uclaf misled the FDA by falsely representing that cefaclor was being manufactured at the production facilities listed in an application relied upon by the FDA when approving the drug for use within the United States. In fact, these persons knew that other facilities in Italy, France, and also in Romania were involved in the manufacture of the drug and that these facilities had not been disclosed to the FDA.

FDA regulators need to know the location where approved drugs are manufactured in part so that they can effectively monitor and inspect the manufacturing facilities and methods used in making pharmaceuticals. Thus, pharmaceutical manufacturers who legally import drugs into the United States are required to create and maintain batch production and control records for each batch of a drug product, consisting of such information as the identity of each active and inactive ingredient used, the location of the manufacturing facility, in-process laboratory control test results, a description of each step in the drug's manufacturing process, and the names of all persons performing and supervising each significant step in the drug's manufacture.

In this case, batch production records at Biochimica Opos' facility falsely misrepresented the production method for cefaclor and falsely showed the manufacturing facilities involved in the production of the drug. In or about May of 1996, members of the conspiracy actually provided false cefaclor batch records to inspectors of the Food and Drug Administration who were conducting an inspection in Biochimica Opos' facility in Agrate Brianza, Italy, and thus willfully misled the Food and Drug Administration about where the cefaclor manufacturing processes were located and how the manufacturing process was being conducted. In addition, a set of false records were kept regarding the manufacturing facilities involved, such as raw material log books, a double software application, and work orders.

United States Attorney Thomas M. DiBiagio stated, "Today's massive criminal penalty sends an unmistakable message to all pharmaceutical companies worldwide. If you plan on selling drugs to the American public, you must play by our rules, whether your company is located inside or outside the United States. This kind of fraud will cost you dearly."

"Quality control of pharmaceuticals distributed in our nation is a top priority," said Assistant Attorney General Robert D. McCallum, Jr., head of the Justice Department's Civil Division. "We will not tolerate any company's efforts to skirt the government's stringent requirements for the sake of profit over the health of our citizens. "