

ENFORCEMENT INFORMATION FOR JULY 5, 2016

Information concerning the civil penalties process is discussed in OFAC regulations governing the various sanctions programs and in 31 C.F.R. part 501. On November 9, 2009, OFAC published as Appendix A to part 501 Economic Sanctions Enforcement Guidelines. 31 C.F.R. part 501, app. A. The Economic Sanctions Enforcement Guidelines, as well as recent final civil penalties and enforcement information, can be found on OFAC's website at www.treasury.gov/ofac/enforcement.

ENTITIES – 31 C.F.R. 501.805(d)(1)(i)

Alcon Laboratories, Inc., Alcon Pharmaceuticals Ltd., and Alcon Management, SA, Settle Potential Civil Liability for Apparent Violations of the Iranian Transactions and Sanctions Regulations and the Sudanese Sanctions Regulations. Alcon Laboratories, Inc., Fort Worth, Texas, Alcon Pharmaceuticals Ltd., Fribourg, Switzerland, and Alcon Management, SA, Genève, Switzerland (collectively, “Alcon”), have agreed to settle potential civil liability with the U.S. Department of the Treasury’s Office of Foreign Assets Control (OFAC) in the amount of \$7,617,150 for apparent violations of the Iranian Transactions and Sanctions Regulations, 31 C.F.R. part 560¹ (ITSR) and the Sudanese Sanctions Regulations, 31 C.F.R. part 538 (SSR). Alcon’s settlement with OFAC is concurrent with its settlement agreement with the Department of Commerce’s Bureau of Industry and Security (BIS). Alcon’s obligation to pay the settlement amount with OFAC will be satisfied by: (a) Alcon’s payment of \$1,317,150 to the U.S. Department of the Treasury, (b) its payment to BIS as set forth in the concurrent settlement agreement with BIS, and (c) its compliance with all other terms set forth in the settlement agreement with BIS.

In the course of BIS’s and OFAC’s investigations, Alcon produced documents and information from which it appeared that from August 2008 to December 2011, Alcon violated section 560.204 of the ITSR on 452 occasions and section 538.205 of the SSR on 61 occasions when it engaged in the sale and exportation of medical end-use surgical and pharmaceutical products from the United States to distributors located in Iran and Sudan without OFAC authorization (the “Apparent Violations”).

OFAC determined that Alcon did not make a voluntary self-disclosure and that the Apparent Violations were not egregious. The statutory maximum civil monetary penalty amount for the Apparent Violations was \$138,982,584 and the base penalty amount for the Apparent Violations was \$16,927,000.

The settlement amount reflects OFAC’s consideration of the following facts and circumstances, pursuant to the General Factors under OFAC’s Economic Sanctions Enforcement Guidelines,

¹ On October 22, 2012, OFAC changed the heading of 31 C.F.R. part 560 from the Iranian Transactions Regulations to the Iranian Transactions and Sanctions Regulations, amended the renamed regulations, and reissued them in their entirety. See 77 Fed. Reg. 64,664 (Oct. 22, 2012). For the sake of clarity, all references herein to the Regulations shall mean the regulations in 31 C.F.R. part 560 in effect at the time of the activity, regardless of whether such activity occurred before or after the regulations were renamed.

31 C.F.R. part 501, app. A: OFAC considered the following to be aggravating factors in this case: (1) Alcon demonstrated reckless disregard for U.S. sanctions requirements by having virtually no compliance program, despite significant business involving the exportation of goods from the United States to Iran and Sudan, and by failing to take adequate steps to investigate a third-party freight forwarder's cessation of shipments to Iran on behalf of Alcon; (2) Alcon and its then-senior management knew of the conduct giving rise to the Apparent Violations; and (3) Alcon is a sophisticated multinational corporation with extensive experience in international trade.

OFAC considered the following to be mitigating factors in this case: (1) harm to U.S. sanctions program objectives was limited because the exports involved medical end-use products that were licensable under the Trade Sanctions Reform and Export Enhancement Act of 2000, and in fact had been previously and subsequently licensed by OFAC for Alcon; (2) Alcon has no prior OFAC sanctions history, including receipt of a Penalty Notice or Finding of Violation in the five years preceding the date of the earliest transaction giving rise to the Apparent Violations, making it eligible for "first violation" mitigation of up to 25 percent; (3) Alcon took remedial action by ceasing the unlicensed exports to sanctioned countries, initiating an internal investigation of the Apparent Violations, and instituting a robust compliance program that now includes: (a) updated or newly-created corporate export and trade sanctions compliance documents, (b) enhanced trade compliance training, and (c) enhanced compliance procedures for requesting OFAC licenses; and (4) Alcon substantially cooperated with OFAC's investigation, including by providing detailed and well-organized information and entering into several statute of limitations tolling agreements with OFAC.

For more information regarding OFAC regulations, please go to: www.treasury.gov/ofac.