

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C. 20436

In the Matter of

**CERTAIN TADALAFIL OR ANY SALT OR
SOLVATE THEREOF AND PRODUCTS
CONTAINING SAME**

Inv. No. 337-TA-539

GENERAL EXCLUSION ORDER

The Commission has determined that there is a violation of section 337 of the Tariff Act of 1930, 19 U.S.C. § 1337, in the unlawful importation and sale of certain tadalafil or any salt or solvate thereof and products containing same that infringe one or more of claims 1-4, 6-8, 12, and 13 of U.S. Patent No. 5,859,006 (“the ‘006 patent”).

Having reviewed the record in this investigation, including the recommended determination of the presiding administrative law judge and the written submissions of the parties, the Commission has made its determinations on the issues of remedy, the public interest, and bonding. The Commission has determined that the appropriate form of relief is a general exclusion order issued under section 337(g)(2), 19 U.S.C. § 1337(g)(2), prohibiting the unlicensed importation of tadalafil or any salt or solvate thereof, and products containing same, covered by one or more of claims 1-4, 6-8, 12, and 13 of the ‘006 patent.

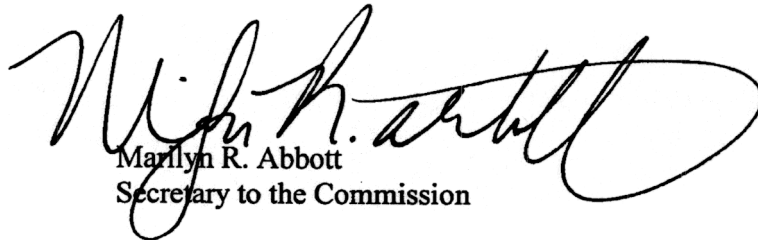
The Commission has also determined that the public interest factors enumerated in 19 U.S.C. § 1337(d) do not preclude issuance of the general exclusion order, and that the bond during the Presidential review period should be in the amount of 100 percent of the entered value

of the products subject to this order. Accordingly, the Commission hereby **ORDERS THAT** :

1. Tadalafil or any salt or solvate thereof and products containing same covered by one or more of claims 1-4, 6-8, 12, and 13 of U.S. Patent No. 5,859,006 are excluded from entry for consumption into the United States, entry for consumption from a foreign trade zone, and withdrawal from a warehouse for consumption, for the remaining term of the patent, except under license of the patent owner or as provided by law.
2. Notwithstanding paragraph 1 of this Order, the aforesaid tadalafil or any salt or solvate thereof and products containing same are entitled to entry for consumption into the United States, entry for consumption from a foreign trade zone, or withdrawal from a warehouse for consumption, under bond in the amount of 100 percent of entered value of such products, pursuant to subsection (j) of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337(j), from the day after this Order is received by the United States Trade Representative, as delegated by the President, 70 *Fed. Reg.* 43251 (July 21, 2005), and until such time as the United States Trade Representative notifies the Commission that this Order is approved or disapproved but, in any event, not later than sixty (60) days after the date of receipt of this Order by the United States Trade Representative.
3. In accordance with 19 U.S.C. § 1337(l), the provisions of this Order shall not apply to products otherwise covered by this Order that are imported by and for the use of the United States, or imported for, and to be used for, the United States with the authorization or consent of the Government.
4. The Commission may modify this Order in accordance with the procedures described in section 210.76 of the Commission's Rules of Practice and Procedure, 19 C.F.R. § 210.76.
5. The Secretary to the Commission shall serve copies of this Order upon each party of record in this investigation and upon the Department of Health and Human Services, the Department of Justice, the Federal Trade Commission, and the Bureau of Customs and Border Protection.

6. Notice of this Order shall be published in the *Federal Register* pursuant to section 337(j)(1)(A) of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337(j)(1)(A) and section 210.49(b) of the Commission's rules of Practice and Procedure (19 C.F.R. § 210.49(b)).

By Order of the Commission.



Marilyn R. Abbott
Secretary to the Commission

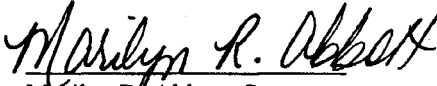
Issued: June 13, 2006

**CERTAIN TADALAFIL OF ANY SALTS OR SOLVATES
THEREOF, AND PRODUCTS CONTAINING SAME**

337-TA-539

CERTIFICATE OF SERVICE

I, Marilyn R. Abbott, hereby certify that the attached **NOTICE OF COMMISSION ISSUANCE OF GENERAL EXCLUSION ORDER; DECISION TO GRANT MOTION TO FILE A SURREPLY; TERMINATION OF INVESTIGATION AND GENERAL EXCLUSION ORDER** has been served on upon all parties and Commission Investigative Attorney, Jay Reiziss, Esq., via first class mail or certified mail on June 13, 2006.


Marilyn R. Abbott, Secretary
U.S. International Trade Commission
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ON BEHALF OF COMPLAINANT
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