Update on Life Sciences Exports to Iran and Sudan

Michael E. Burke

On September 28, the Office of Foreign Assets Control (OFAC) at the U.S. Department of the Treasury issued its *Biennial Report of Licensing Activities Pursuant to the Trade Sanctions Reform and Export Enhancement Act of 2000*, detailing its licensing activities for exports of medicine and medical devices to Iran and Sudan under that statute. The Report illuminates OFAC's process for reviewing, and potentially approving, export license applications filed by U.S. exporters—particularly life sciences companies—for specific exports to Iran and Sudan.

As life sciences companies know, the U.S. government maintains a comprehensive economic sanction and embargo program against both Iran and Sudan. Under those programs, administered by OFAC, it is illegal for U.S. companies to conduct any business with or in Iran and Sudan, without first obtaining an appropriate license. While OFAC's general policy is deny most such applications, the licensing process under the Trade Sanctions Reform and Export Enhancement Act of 2000 (TSRA) operates as an exception to the economic sanction and embargo programs and to OFAC's general policy of denial. In specific cases, and upon application to OFAC through the TSRA process, a U.S. life sciences company may be granted a one-year license to export specific of medicine and medical devices to Iran and Sudan. The license is 'somewhat' renewable, in that exporters must re-file the TSRA application to extend the term of that license. Life sciences companies should also be aware that their product should be classified as EAR99 by the Bureau of Industry and Security (BIS) at the U.S. Department of Commerce, and be on an OFAC 'approved' list, prior to filing the TSRA application.

Relevant facts:

- In the reporting period, there were 2,583 license applications under the TSRA, a 19.1% decrease over the previous reporting period.
- Of those 2,583 applications, OFAC issued 1,332 licenses and 392 license amendments.
- On average, licenses were issued within sixty-four (64) business days, and license amendments were issued within seventeen (17) business days of receipt.
- In the reporting period, 89.7% of applications (86.5% of all approvals) were for Iran, and 10.3% (13.5% of all approvals) for Sudan.
- 75.7% of the applications and 80.5% of the approval were for the export of medical devices.

AGG Observations:

- Even though there have been some recent, and significant changes to US export control regulations affecting Sudan and Iran, the TSRA mechanism is the easiest, and most predictable way for U.S. life sciences to access those markets in a manner consistent with U.S. law.
- Comparatively speaking, Iran remains a larger market for U.S. life sciences products than Sudan.

- Before starting the TSRA process, U.S. life sciences exporters should verify that their product is on an approved list maintained by OFAC—note that this approved list is not the same as obtaining an EAR99 classification from BIS.

- Timing is important- a U.S. life sciences exporter needs to obtain a commodity classification for their medicine and device product(s) from BIS prior to filing the TSRA application. BIS review can take thirty (30) days, the the TSRA process, on average, takes sixty-four (64) business days. All of this means that a U.S. life sciences exporter should start the TSRA process about one hundred and twenty (120) days prior to the date of its intended first export to Iran or Sudan.

- Similarly, U.S. life sciences exporters should budget at least ninety (90) days for renewals of their TSRA license, since such licenses have a one-year term.

- U.S. life sciences exporters should be aware that they may not deal, in any manner, with certain Iranian banks, even on letter of credit issues.

Authors and Contributors

Michael E. Burke
Partner, DC Office
202.677.4046
michael.burke@agg.com

not *if*, but *how*.®

About Arnall Golden Gregory LLP

Arnall Golden Gregory, a law firm with more than 150 attorneys in Atlanta and Washington, DC, employs a "business sensibility" approach, developing a deep understanding of each client's industry and situation in order to find a customized, cost-sensitive solution, and then continuing to help them stay one step ahead. Selected for The National Law Journal's prestigious 2013 Midsize Hot List, the firm offers corporate, litigation and regulatory services for numerous industries, including healthcare, life sciences, global logistics and transportation, real estate, food distribution, financial services, franchising, consumer products and services, information services, energy and manufacturing. AGG subscribes to the belief "not if, but how.®" Visit www.agg.com.

Atlanta Office
171 17th Street, NW
Suite 2100
Atlanta, GA 30363

Washington, DC Office
1775 Pennsylvania Avenue, NW
Suite 1000
Washington, DC 20006

To subscribe to future alerts, insights and newsletters: **http://www.agg.com/subscribe/**