UNITED STATES PUBLIC HEALTH SERVICE
TECHNOLOGY TRANSFER POLICY MANUAL

Chapter No. 309

PHS Policy for Handling Requests Related to the U.S. Manufacturing Requirement for PHS Inventions

A. PURPOSE

This Manual Chapter establishes the Public Health Service (PHS) policy for handling requests related to the application of the U.S. manufacturing requirement by PHS license applicants or licensees.

B. BACKGROUND

PHS licenses for Government inventions generally require that any products embodying the invention, or produced through the use of the invention (e.g., products made through the use of an invention directed to a method), are manufactured substantially in the United States.

C. POLICY

Under 35 U.S.C. § 209(b):

> A Federal agency shall normally grant the right to use or sell any federally-owned invention in the United States to a licensee that agrees that any products embodying the invention or produced through the use of the invention will be manufactured substantially in the United States.

Consistent with 37 C.F.R. § 404.5(a)(2), requests for deviations from the U.S. manufacturing requirement may be granted upon a determination by PHS that either 1) reasonable but unsuccessful efforts have been made to license the invention to a company with a U.S. manufacturing capability; or 2) that under the circumstances, domestic manufacture is not commercially feasible.

Requests for deviations from the U.S. manufacturing requirement in connection with licensing of NIH inventions should be directed to the NIH Office of Technology Transfer's (NIH OTT) Division of Technology Development and Transfer (DTDT) and are decided by the Director, DTDT. As designated by FDA, through the FDA Technology Development Officer, requests for deviations from the U.S. manufacturing requirement in connection with licensing of FDA inventions should be directed to NIH OTT, DTDT, and are decided by Director, DTDT. Requests for deviations from the U.S. manufacturing requirement in connection with licenses to CDC inventions should be directed to the CDC Technology Transfer Office (CDC TTO) and are decided by the Director, CDC TTO.

D. EFFECTIVE DATE

The policy set forth in this Manual Chapter is effective December 8, 2010, and supersedes in its entirety PHS Technology Transfer Policy Manual Chapter 309, which was first approved on September 30, 1994.

E. ADDITIONAL INFORMATION

For more information on this Manual Chapter, contact the Office of Technology Transfer, NIH, (301) 496-7057 or http://www.ott.nih.gov/contact-us .