# DRAFT LEGISLATIVE LANGUAGE*

## SEC. XXX. DRUGS FOR LIMITED USE IN PATIENTS WITH SERIOUS OR LIFE-THREATENING BACTERIAL INFECTIONS

### (XX) ANTIBACTERIAL DRUGS FOR LIMITED USE IN POPULATIONS OF PATIENTS WITH SERIOUS OR LIFE-THREATENING INFECTIONS

(1) IN GENERAL.—The Secretary may approve a drug under section 505(c) or section 351 of the Public Health Service Act as a limited population antibacterial drug if:

(A) the drug is intended for the treatment of a serious or life-threatening infectious disease caused by one or more bacterial pathogens,

(B) the drug demonstrates the potential to address an unmet medical need,

(C) the benefits of approving the drug in a population of patients with such infection outweighs the risks and accepting greater known risk or uncertainty about potential risk associated with the drug in the population is justified by the severity of the infection and the unmet medical need; and

(D) all of the requirements of section 505(c) or section 351 of the Public Health Service Act are met.

(E) The authority to approve limited population antibacterial drugs may not be delegated below the level of the Director, Center for Drug Evaluation and Research, or the Director, Center for Biologics Evaluation and Research.

(2) CONDITIONS OF APPROVAL.—Approval of an antibacterial product for use in a limited population under this subsection shall be subject to the following requirements:

(A) All labeling for a drug approved under this subsection shall prominently and conspicuously bear the words “Limited Population Antibacterial Drug” or a symbol, designated by the Secretary, that conveys that the drug was approved for limited use in said population, or both.

(B) The Indication section of the labeling for a drug approved under this subsection shall state, “This antibacterial drug has been approved for use in a limited population of patients with serious or life-threatening infections where limited alternative therapies are available. The safety and efficacy of the drug has not been established beyond this limited population. Therefore the drug should only be used in patients whose clinical condition warrants treatment with this drug.” A description of the population to which the approval is limited shall be included in the Indication section.

(C) The sponsor shall submit copies of all promotional materials related to the product during the preapproval review period and, following approval for such period thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials. This limitation shall be lifted upon approval of a supplemental application that expands the use of the drug to a population for which no limitations on use are required.

(3) REQUEST FOR DESIGNATION.—A sponsor of a new antibacterial drug may request the Secretary to designate the drug as potentially eligible for limited population status. A request to designate a drug as potentially eligible for such status may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

(4) DESIGNATION.—Within 60 calendar days after the receipt of a request under subparagraph (3), the Secretary shall determine whether the drug that is the subject of the request has the potential to be approved as a limited population antibacterial drug, and if so, the Secretary shall designate the drug as such.
(5) ADVICE.—The Secretary shall provide prompt advice to the sponsor of a drug designated as potentially eligible for limited population status as the sponsor plans its development program to obtain the necessary data for approval and any additional studies that would be required to expand the use to a broader population.

*Formerly known as “Special Population Limited Medical Use [SPLMU] Drugs”; now narrowed to cover only antibacterial drugs only and now known as “Limited Population Antibacterial Drugs”