



U.S. FOOD & DRUG
ADMINISTRATION

Memorandum

DATE: June 2, 2022

TO: Memo to File

FROM: Alisa Gilliard, Pharm.D., Consumer Safety Officer
CBER/OCBQ/DCM/APLB

THROUGH: Lisa Stockbridge, Ph.D., Branch Chief
CBER/OCBQ/DCM/APLB

Robert Sausville, Division Director
CBER/OCBQ/DCM

SUBJECT: APLB Labeling Review for PRIORIX
BLA 125748
Applicant: GlaxoSmithKline Biologicals

APLB Summary Statement for SBRA

The proprietary name, PRIORIX, was reviewed by CBER's Advertising and Promotional Labeling Branch (APLB) on April 5, 2022, and found to be acceptable. CBER communicated this decision to the Applicant on May 2, 2022.

In our review, dated April 26, 2022, APLB examined the prescribing information, package, and container labels from a promotional and comprehension perspective. The package and container labels were found acceptable. On June 1, 2022, following an iterative review of additional revisions requested by the review committee, the applicant provided prescribing information that is acceptable from a promotional and comprehension perspective.