

Attachment D: Wholesale Importation Drug List

This attachment incorporates by file a document for each drug identified below. For each drug, the Agency intends to import all strengths and dosage forms listed on the cover sheet. The Agency does not intend to import any approved dosage form or strength combination not listed on the cover sheets. Each file contains:

- **A drug label cover sheet** providing each eligible prescription drug's FDA-approved counterpart, the manufacturer(s) of the finished dosage form and the active ingredient or ingredients of each eligible prescription drug that the SIP Sponsor seeks to import, the legal relationship of these entities to the SIP Sponsor, and information about the HPFB-approved product and its FDA-approved counterpart. Unless otherwise specified, information on each of the cover sheets, including proprietary/brand names, active ingredients, inactive ingredients, and dosage forms, are identical for both HPFB- and FDA-approved products and will not be listed separately. Ingredient names referring to the same chemical entity may be different between HPFB-approved monographs and FDA-approved labels. A list of such entities will be provided at the end of this document.
- **The proposed label and side-by-side comparison** of proposed label to FDA-approved drug label, including the Prescribing Information, carton and container labeling, and patient labeling (e.g., Medication Guide, Instructions for Use, patient package inserts), with all differences annotated and explained.
- **The proposed package insert.**
- **The FDA-approved package insert.**
- **The HPFB-approved package insert.**
- **Marketing Status in the United States.**

Drug Name

Biktarvy	Descovy	Dovato
Genvoya	Juluca	Odefsey
Prezcobix	Prezista	Ravicti
Rexulti	Symtuza	Tivicay
Vraylar	Xtandi	

Interchangeable chemical names:

Each row represents all listed names for the same chemical entity separated by semicolon.

- Tenofovir alafenamide fumarate; Tenofovir alafenamide hemifumarate
- Macrogol, PEG; Polyethylene glycol
- Sunset yellow FCF aluminum lake; FD&C Yellow No. 6
- Ferric oxide; Iron oxide
- HCl; Hydrochloride
- Caprylocaproyl macrogolglycerides, Caprylocaproyl polyoxyglycerides
- Glycerol; Glycerin