

U.S. Food & Drug Administration

Import Alert 66-60

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Import Alert # 66-60

Published Date: 03/18/2011

Type: DWPE

Import Alert Name:

"Detention Without Physical Examination of Certain Steroid Alternatives"

Reason for Alert:

Unapproved alternatives to anabolic steroids have commonly been found to present serious safety and effectiveness concerns. In February, 1991, anabolic steroids became controlled substances. This is one factor which has stimulated the market for imported steroid alternatives.

Guidance:

Districts may detain without physical examination all shipments of finished dosage forms (both commercial and personal) of the cited unapproved products. Do not collect samples for laboratory analysis. Districts should determine whether the drugs are covered by a current approved NDA or IND. Those products covered by an approved NDA or IND should be released.

Bulk forms of these drugs may be detained under certain circumstances as misbranded drugs; however, prior to initiating any action against bulk pharmaceutical chemicals, contact CDER's Import/Export Branch.

Product Description:

Foreign manufactured unapproved drugs promoted as alternatives to certain anabolic steroids i.e.,

* Yohimbe Bark or Yohimbe Bark Extract

* Cyclofenil

* Gamma Hydroxybutyrate (GHB)

* Diosgenin

* Clenbuterol

Charge:

"The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a new drug within the meaning of Section 201(p) without an approved new drug application [Unapproved New Drug, Section 505(a)]."

OASIS Charge Code - UNAPPROVED

Countries

MULTIPLE COUNTRIES (PODS ONLY)

(60 D - - 99) Adrenocortical Steroid N.E.C.

Notes: Yohimbe Bark or Yohimbe Bark Extract Cyclofenil Gamma Hydroxybutyrate (GHB) Diosgenin Clenbuterol

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