Import Alert 54-16

(Note: This import alert represents the Agency’s current guidance to FDA field personnel regarding the manufacturer(s) and/or products(s) at issue. It does not create or confer any rights for or on any person, and does not operate to bind FDA or the public).

Import Alert # 54-16
Published Date: 07/07/2015
Type: DWPE
Import Alert Name:
”DETENTION WITHOUT PHYSICAL EXAMINATION OF PRODUCTS THAT ARE MARKETED AS FOODS, INCLUDING PRODUCTS MARKETED AS DIETARY SUPPLEMENTS, THAT CONTAIN AN ACTIVE PHARMACEUTICAL INGREDIENT”

Reason for Alert:
FDA field investigations and laboratory analyses have concluded that a number of imported products marketed as dietary supplements that are often promoted for sexual enhancement, weight loss, muscle building, lifestyle, and other claims, contain undeclared active pharmaceutical ingredients (APIs).

FDA investigations find the APIs include:
- anticoagulants (e.g., Warfarin)
- anticonvulsants (e.g., Phenytoin)
- HMG-CoA reductase inhibitors (e.g., Lovastatin),
- Phosphodiesterase type 5 inhibitors (e.g., Sildenafil)
- prescription nonsteroidal anti-inflammatory drugs (NSAIDS) (e.g., Indomethacin)
- beta-blockers (e.g., Propranolol)
- controlled substances (Benzodiazepines and anabolic steroids)
- APIs removed from the market for reasons of safety or efficacy (e.g., Sibutramine)
- novel synthetic steroids, and new chemicals ingredients of unknown safety and efficacy.

These APIs, because of their toxicity or other potential for harmful effect, or the method of their use, or the collateral measures necessary for their use, are not safe for use except under the supervision of a practitioner licensed by law to administer such products.

FDA analyses and investigations revealed that these products frequently contain the same APIs, or analogues of APIs, that are in FDA-approved drugs. Depending on the circumstances, these products are misbranded and unapproved new drugs, or adulterated food under the Federal Food, Drug, and Cosmetic Act.

Guidance:
Districts may detain without physical examination the specified products from the firms listed in the Red List of this import alert.

Districts should submit a recommendation for addition to the Red List when detained products appear to meet the criteria in this alert, and are not listed on the Red list of this import alert. DIO and FDA’s Center for Drug Evaluation and Research (CDER) or FDA’s Center for Food Safety and Applied Nutrition (CFSAN) will evaluate regulatory recommendations on a case-by-case basis.

For any product purporting to be or otherwise marketed as a food, including a product marketed as a dietary supplement that is not covered by an approved new drug application (NDA), an approved abbreviated new drug application (ANDA), or other limited exemptions under the Federal Food, Drug, and Cosmetic Act (and applicable regulations) from the requirement for an approved application, and contains an API, or an analogue of an API described above, misbranded drug and unapproved new drug, or adulterated food charges may be appropriate based on the criteria described below.

Unapproved new drug and misbranded drug
For any product purporting to be or otherwise marketed as a food, including a product marketed as a dietary supplement, whose labeling indicates that the product appears to be intended for use as a drug, under Section 201(g)(1)(B), the unapproved new drug [Section 505(a)] and misbranded drug [Section 502(f)(1) & (f)(2)] charges are appropriate.

For a product purporting to be or otherwise marketed as a food, including a product marketed as a dietary supplement, that is excluded from the definition of a dietary supplement under Section 201(ff)(3)(B) and whose labeling indicates that the product appears to be intended for use as a drug, under Section 201(g)(1)(C), the unapproved new drug [Section 505(a)] and misbranded drug [Section 502(f)(1) & (f)(2)] charges are appropriate.

Adulterated food
For a product purporting to be or otherwise marketed as a food, including a product marketed as a dietary supplement, but whose
labeling does not indicate that the product appears to be intended for use as a drug, the adulterated food [Section 402(a)(2)(c)] charge is appropriate because the APIs of the type identified above are unsafe food additives within the meaning of section 409 of the Act. A food product to which such an API is added is considered to be adulterated as defined in section 402(a)(2)(c) of the Act. The APIs of the type identified above also represent a poisonous or deleterious substance in food; therefore the adulterated food [Section 402(a)(1)] charge is also appropriate.

INFORMATION FOR FIRMS REQUESTING REMOVAL FROM THE RED LIST:

In order to be removed from the red list, the firm should submit evidence to FDA establishing that the conditions that gave rise to the appearance of the violation have been resolved, so that the agency will have confidence that future entries will be in compliance with the Act.

For additional guidance on removal from detention without physical examination, refer to FDA's Regulatory Procedures Manual, Chapter 9, Section 9-6, "Detention Without Physical Examination (DWPE)."

All requests for removal from detention without physical examination may be sent via email to: importalerts2@fda.hhs.gov

Or mailed to:

Food and Drug Administration
Division of Import Operations
12420 Parklawn Drive, ELEM-3109
Rockville, MD 20857

Requests for removal from detention without physical examination will be reviewed by DIO and referred to CDER Imports Exports Compliance Branch or CFSAN Office of Compliance, Division of Enforcement, Labeling and Dietary Supplement Compliance Branch for additional evaluation. The Center will review analytical data, labels, and labeling submitted in support of removal of products from detention without physical examination.

For questions or issues involving import operations, contact DIO's Import Operations and Maintenance Branch at (301) 796-0356.

For questions or issues concerning science, science policy, sample collection, analysis, preparation, or analytical methodology, contact the Office of Regulatory Science at (301) 796-6600.

Product Description:

PRODUCTS: Dietary Supplements
Unapproved New Drugs
Misbranded Drugs

PRODUCT CODE: "See Red List"

PROBLEM: Unapproved New Drugs; Misbranded Drugs,
Unapproved Food Additive; Adulterated Food

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 effective new drug application (NDA)[Unapproved New Drug, Section 505(a)]"

OASIS Charge Code: UNAPPROVED

"The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a drug within the meaning of Section 201(g) that lacks adequate directions for use. [Misbranded, Section 502(f)(1)]"

OASIS Charge Code: DIRECTIONS

"The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be adulterated because it appears to contain a poisonous or deleterious substance which may render it injurious to health [Adulteration, Section 402(a)(1)]"

OASIS Charge Code: POISONOUS

"The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be adulterated because it appears to bear or contain a food additive that is unsafe within the meaning of Section 409 [Adulteration, Section 402(a)(2)(C)]"

OASIS Charge Code: UNSAFE ADD

List of firms and their products subject to Detention without Physical Examination (DWPE) under this Import Alert (a.k.a. Red List)

Michelle Gleneuine
Av. Canal Marapendi No, 4100 / 1105 BL1, Rio de Janeiro, RJ BRAZIL

Date Published : 05/11/2015

Notes: Product contains undeclared Fenproporex HCL and Chlordiazepoxide HCL.


Date Published: 05/11/2015

http://www.accessdata.fda.gov/cms_ia/importalert_1141.html
Desc: PEB One and PEB Two Capsules (Brand Renutryent) Dietary Supplement  
Notes: Product contains undeclared Fenproporex HCL and Chlordiazepoxide HCL.

**CANADA**

**Nugale Pharmaceutical Inc**  
41 Pullman Crt, Toronto, ONTARIO CANADA  
54 Y - - 99 Vitamin, Mineral, Proteins and Unconventional Dietary Specialities For Humans and Animals, N.E.C.  
Notes: Slimquick Green Coffee Bean Softgel  
Date Published: 04/14/2015

**BEIJING JIANYANG HEALTH PRODUCT CO., LTD**  
LIremen street, BEIGING, CN-11 CHINA  
54 F - - 99 Herbals & Botanicals (not Teas), N.E.C.  
Notes: Super Shanghai Strong Testis Capsules "Dietary Supplement"  
Date Published: 05/07/2015

**Beijing Kowloon Pharmaceutical Factory**  
No 1200 Diyang Bldg, BEIJING, CHINA  
54 C - - 02 L-Arginine (Protein)  
Notes: 4Everon Sexual Stimulant Tablets (declared as L-Arginine dietary supplement)  
Date Published: 06/29/2015

**ELT Technology**  
10f Tech-Building East Heping Road, Longhua Street, Baoan District Shenzhen, Guangdong, CHINA  
31 - - - Coffee/Tea  
Notes: Lose Weight Coffee Slim Delicious  
Date Published: 04/17/2015

**Eagene Biotechnology Co., Ltd.**  
Room 1301, Block A, China World Trade, Center, No. 41, Minzu Avenue, Nanning, CN-45 CHINA  
54 G - - 99 Animal By-Products and Extracts, N.E.C.  
Notes: Rocket Fuel (Oyster Peptide Tablets)  
Date Published: 05/12/2015

**Guangzhou Garden City (Biological) Health Food Factory**  
No. 128 Guangzhou Avenue, Dasan Industrial Park North, Guangzhou, CHINA  
54 Y - - 99 Vitamin, Mineral, Proteins and Unconventional Dietary Specialities For Humans and Animals, N.E.C.  
Notes: La Jiao Shou Shen  
Date Published: 04/13/2015

**CHINA**

**BEIJING JIANYANG HEALTH PRODUCT CO., LTD**  
LIremen street, BEIGING, CN-11 CHINA  
54 F - - 99 Herbals & Botanicals (not Teas), N.E.C.  
Notes: Super Shanghai Strong Testis Capsules "Dietary Supplement"  
Date Published: 05/07/2015

**Beijing Kowloon Pharmaceutical Factory**  
No 1200 Diyang Bldg, BEIJING, CHINA  
54 C - - 02 L-Arginine (Protein)  
Notes: 4Everon Sexual Stimulant Tablets (declared as L-Arginine dietary supplement)  
Date Published: 06/29/2015

**Eagene Biotechnology Co., Ltd.**  
Room 1301, Block A, China World Trade, Center, No. 41, Minzu Avenue, Nanning, CN-45 CHINA  
54 G - - 99 Animal By-Products and Extracts, N.E.C.  
Notes: Rocket Fuel (Oyster Peptide Tablets)  
Date Published: 05/12/2015

**Guangzhou Garden City (Biological) Health Food Factory**  
No. 128 Guangzhou Avenue, Dasan Industrial Park North, Guangzhou, CHINA  
54 Y - - 99 Vitamin, Mineral, Proteins and Unconventional Dietary Specialities For Humans and Animals, N.E.C.  
Notes: La Jiao Shou Shen  
Date Published: 04/13/2015

---

http://www.accessdata.fda.gov/cms_ia/importalert_1141.html

3/7
Notes: Product contains undeclared sibutramine and phenolphthalein.

**Guangzhou Meilai Biotechnology Co., Ltd.**  
**No.128 North Guangzhou Ave, Chashan Industrial Park, Guangzhou, CHINA**  
54 Y - - 99 Vitamin, Mineral, Proteins and Unconventional Dietary Specialties For Humans and Animals, N.E.C.  
Desc: La Jiao Shou Shen  
Notes: Product contains undeclared sibutramine and phenolphthalein  
Date Published: 04/23/2015

**Guangzhou Yan Xiang Co, LTD**  
**105 Shahe Rd., Baiyun Guangzhou, Guangdong CHINA**  
54 Y - - 06 Bee Pollen (Vit/Min/Protein/Unconventional Dietary Spec for Human/Animal, N.E.C.)  
Desc: Ultimate Formula Bee Pollen Capsules  
Notes: FDA analysis found undeclared Sibutramine in product.  
60 R - - 19 Sibutramine HCL Monohydrate (Anorexic)  
Desc: Ultimate Formula Bee Pollen Capsules  
Notes: FDA analysis found undeclared Sibutramine in product  
Desc: Ultimate Formula Bee Pollen Capsules  
Notes: FDA analysis found undeclared Sibutramine in product  
Date Published: 05/19/2015

**Kunming DaLi Industry & Trade Co., Ltd**  
**372 West Renmin Road, Kunming, Yunnan, Cn-53 CHINA**  
54 Y - -- Vit/Min/Prot/Unconv Diet(Human/Animal)  
55 - - - - Pharm Necess & Ctnr For Drug/Bio  
60 - - - - Human and Animal Drugs  
61 - - - - Human and Animal Drugs  
62 - - - - Human and Animal Drugs  
63 - - - - Human and Animal Drugs  
64 - - - - Human and Animal Drugs  
65 - - - - Human and Animal Drugs  
66 - - - - Human and Animal Drugs  
Notes: All Drug Products; Problem(s): APIs found in dietary supplement products  
Date Published: 04/01/2015

**La Sha City Limited Company**  
**La Sha City Liberation Road no. 168, La Sha City, Tibet CHINA**  
54 Y - - 99 Vitamin, Mineral, Proteins and Unconventional Dietary Specialties For Humans and Animals, N.E.C.  
Desc: France T253 Tablets  
Notes: Problem(s); Sildenafil found in product  
65 P - - 02 Sildenafil Citrate (Regulator)  
Desc: France T253 Tablets  
Notes: Problem(s); Sildenafil found in product  
Desc: France T253 Tablets  
Notes: Problem(s); Sildenafil found in product  
Date Published: 05/15/2015

**Much New Limited**  
**8 STORY HUANGYAN MANSION, Huanghai, Zhejiangsheng CHINA**  
54 Y - - 99 Vitamin, Mineral, Proteins and Unconventional Dietary Specialties For Humans and Animals, N.E.C.  
Desc: Joyful Slim (Puerarin- Chinese Yim Powder)  
Notes: Slim 30 was found to contain undeclared Desmethyl Sibutramine  
Date Published: 07/07/2015

---

http://www.accessdata.fda.gov/cms_ia/importalert_1141.html
8/18/2015

Notes: Slim 30 was found to contain undeclared Desmethyl Sibutramine
Desc: Slim 30 (Natural Herb Supplement for weight loss)

NET D ACTIVE NUTRA TRADING CO.
15 YONGJIANG ROAD , BEILUN NETD , NINGBO, Cn-Nota CHINA
54 Y - 99 Vitamin, Mineral, Proteins and Unconventional Dietary Specialties For Humans and Animals, N.E.C.
Desc: Blue Steel Dietary Supplement
Notes: Product contains undeclared Thianone; an analog of Sildenafil
Desc: Blue Steel Dietary Supplement
Notes: Product contains undeclared Thianone; an analog of Sildenafil

No. 8 IIAley
xia shi wei district , hu yong town baon district , guangdong, CHINA
54 - - - - Vit/Min/Prot/Unconv Diet(Human/Animal)
Notes: All Dietary Supplements; APIs found in dietary supplement products
55 - - - - Pharm Necess & Ctnr For Drug/Bio
Notes: All Drug Products; APIs found in dietary supplement products
60 - - - - Human and Animal Drugs
Notes: All Drug Products; APIs found in dietary supplement products
61 - - - - Human and Animal Drugs
Notes: All Drug Products; APIs found in dietary supplement products
62 - - - - Human and Animal Drugs
Notes: All Drug Products; APIs found in dietary supplement products
63 - - - - Human and Animal Drugs
Notes: All Drug Products; APIs found in dietary supplement products
64 - - - - Human and Animal Drugs
Notes: All Drug Products; APIs found in dietary supplement products
65 - - - - Human and Animal Drugs
Notes: All Drug Products; APIs found in dietary supplement products
66 - - - - Human and Animal Drugs
Notes: All Drug Products; APIs found in dietary supplement products

xuancheng baicao plants industry and trade co.,ltd
xuancheng economic developing zone , Anhui, Anweisheng CHINA
54 E - - - - Herbal and Botanical
Desc: Super ArthGold
Notes: Undeclared APIs
54 E - - - - Herbal and Botanical
Desc: Pro ArthMax
Notes: Undeclared APIs

HONG KONG
Hong Kong Tianlong Technology International Group Company
20/F , Hua Chiao Commercial Centre , Mong Kok, Kowloon HONG KONG
54 Y - 99 Vitamin, Mineral, Proteins and Unconventional Dietary Specialties For Humans and Animals, N.E.C.
Desc: France T253 Tablets
Notes: Problem(s); Sildenafil found in product.
65 P - 02 Sildenafil Citrate (Regulator)
Desc: France T253 Tablets
Notes: Problem(s); Sildenafil found in product
Desc: France T253 Tablets
Notes: Problem(s); Sildenafil found in product
66 Y - 99 Exhibits - Other Drug Related Items N.E.C.
Desc: France T253 Tablets
Notes: Problem(s); Sildenafil found in product

Hong Kong Tianlong Technology International Group Company
20/F , Hua Chiao Commercial Centre , Mong Kok, Kowloon HONG KONG
54 Y - 99 Vitamin, Mineral, Proteins and Unconventional Dietary Specialties For Humans and Animals, N.E.C.
Desc: France T253 Tablets
Notes: Problem(s); Sildenafil found in product.
65 P - 02 Sildenafil Citrate (Regulator)
Notes: Problem(s); Sildenafil found in product.

Notes: Slim 30 was found to contain undeclared Desmethyl Sibutramine
Desc: Slim 30 (Natural Herb Supplement for weight loss)

http://www.accessdata.fda.gov/cms_ia/importalert_1141.html
Desc: France T253 Tablets
Notes: Sildenafil found in product

Desc: France T253 Tablets
Notes: Sildenafil found in product

66 Y – - 99 Exhibits - Other Drug Related Items N.E.C.
Desc: France T253 Tablets
Notes: Sildenafil found in product

Hongkong Jiuyuejiu Biology Technology CO., LTD

1226, Tsim Sha Tsui, Unknown, HONG KONG

Date Published: 06/01/2015

54 Y – - 99 Vitamin, Mineral, Proteins and Unconventional Dietary Specialities For Humans and Animals, N.E.C.
Desc: Bull Tablets
Notes: Sildenafil and Tadalafil found in product.

65 P – - 02 Sildenafil Citrate (Regulator)
Desc: Bull Tablets
Notes: Sildenafil and Tadalafil found in product.

66 S – - 51 Tadalafil
Desc: Bull Tablets
Notes: Sildenafil and Tadalafil found in product.

Desc: Bull Tablets
Notes: Sildenafil and Tadalafil found in product.

KOREA, REPUBLIC OF (SOUTH)

Date Published: 06/30/2015

Dae Han Corporation

703 Sungwoo Starus, 16 Gumi-Ro, Bundang-Gu, Seongnam-si, KYONGGI KOREA, REPUBLIC OF (SOUTH)

Date Published: 06/30/2015

54 Y – - 99 Vitamin, Mineral, Proteins and Unconventional Dietary Specialities For Humans and Animals, N.E.C.
Desc: Power Khan Pills
Notes: Undeclared Sulfoaidenafil and Acetildenafil

Links on this page:


Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

- Accessibility
- Contact FDA
- Careers
- FDA Basics
- FOIA
- No Fear Act
- Site Map
- Transparency
- Website Policies

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Email FDA

http://www.accessdata.fda.gov/cms_ia/importalert_1141.html
Links on this page: