

<b>Violation Code</b>	<b>Section</b>	<b>Charge Statement</b>
807REFUSAL	807(b)	The food is subject to refusal of admission pursuant to Section 807 in that the foreign factory, warehouse, or other establishment of which the owner, operator, or agent in charge, or the government of the foreign country, refuses to permit entry of United States inspectors or other individuals duly designated by the Secretary, upon request, to inspect such factory, warehouse, or other establishment.
ADDED BULK	402(b)(4), 801(a)(3); ADULTERATION	The food appears to have a substance added to, mixed or packed with it so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.
AFLATOXIN	402(a)(1), 801(a)(3); ADULTERATION	The article appears to contain a mycotoxin, a poisonous and deleterious substance which may render it injurious to health.
AF-NONRSP	402(a)(4), 801(a) (3);ADULTERATION	The article appears to have been prepared or packed under insanitary conditions whereby it may have been rendered injurious to health due to inadequate processing in that the scheduled process filed by the manufacturer for this acidified food pursuant to 21 CFR 108.25 (c)(2) appears to be inadequate to protect the public health.
AGRINSULIN	801(d)(1), (2);IMPORTATION RESTRICTED	The article appears to be composed wholly or partly of insulin manufactured in the US and offered for import by other than the manufacturer and reimportation does not appear to have been authorized by the Secretary for a medical emergency
AGR RX	801(d)(1),(2); IMPORTATION RESTRICTED	The article appears to be a prescription drug manufactured in the U.S. and offered for import by other than the manufacturer and reimportation does not appear to have been authorized by the Secretary for use in a medical emergency.
ALCOHOL	402(d)(2), 801(a)(3); ADULTERATION	The article appears to be a confectionary that bears or contains alcohol in excess of 1/2 of 1% by volume derived solely from the use of flavoring extracts.
ALLERGEN	403(w) 801(a)(3); Misbranding	the label fails to declare all major food allergens present in the product, as required by section 403(w)(1).
ALRGN402A4	801(a)(3); 402(a)4; Adulterated	it appears to be adulterated within the meaning of section 402(a)(4) because it appears that the food was prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health, specifically because the food appears to contain a major food allergen through insanitary conditions that led to cross-contact. [Adulteration, Section 402(a)(4)]

ANDRO	402(f)(1)(B),801(a)(3);ADULTERATION	The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to declare and/or contain androstenedione, a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury [Adulteration, Section 402(f)(1)(B)]
BACTERIA	402(a)(1), 801(a)(3); ADULTERATION	The article appears to contain a poisonous and deleterious substance which may render it injurious to health. Contains
BANNED	501(g), 801(a)(3); ADULTERATION	The article appears to be a banned device.
BIO TOXIN	402(a)(1), 801(a)(3), Adulteration	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to contain a poisonous and deleterious substance which would ordinarily render it injurious to health. Appears to contain
BSE DRUGS	501(a)(2)(A), 801(a)(1); Adulteration	The article is subject to refusal of admission pursuant to Section 801(a)(1) in that it appears to have been prepared, packed or held under insanitary conditions whereby it may have been rendered injurious to health.
BSE FILTH	402(a)(3), 801(a)(3); Adulteration	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be unfit for food.
BUTTER	402(e), 801(a)(3); ADULTERATION	The article appears to be oleo/margarine or butter with raw materials consisting in whole or in part of a filthy, putrid, or decomposed substance or the article is otherwise be unfit for food.
CALIBRATED	502(f)(1); 801(a)(3), misbranding	The article is subject to refusal in that it is calibrated in units not commonly used in the United States
CHLORAMP	402(a)(2)(C)(i), 801(a)(3); ADULTERATION	The article appears to contain a food additive, namely chloramphenicol, that is unsafe within the meaning of 21 U.S.C. 348.
CHOKER HZRD	402(a)(3), 801(a)(3); ADULTERATION	The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be unfit for food, because it contains a foreign object which may pose a choking hazard. [Adulteration 402(a)(3)].
COL ADDED	501(a)(4)(A), 801(a)(3); ADULTERATION	The article appears to bear or contain, for the purpose of coloring only, a color additive which is unsafe within the meaning of Section 721(a).
COLOR LBLG	403(k), 801(a)(3); MISBRANDING	The article appears to contain an artificial coloring and it fails to bear labeling stating that fact.

COLOR LBLG	602(e), 801(a)(3); MISBRANDING	The color additive appears to not have its packaging and labeling in conformity with such requirements as issued under section 721.
CONCEALED	402(b)(3), 801(a)(3); ADULTERATION	It appears to be food which has damage or inferiority concealed in any manner.
CONTAINER	402(a)(6), 801(a)(3); ADULTERATION	The container appears to be composed, in whole or in part, of a poisonous or deleterious substance which may render the contents injurious to health.
CONTAINER	501(a)(3), 801(a)(3); ADULTERATION	The container appears to be composed, in whole or in part, of a poisonous or deleterious substance which may render the contents injurious to health.
CONTAINER	601(d), 801(a)(3); ADULTERATION	The container appears to be composed, in whole or in part, of a poisonous or deleterious substance which may render the contents injurious to health.
CONTAM CAN	402(a)(1), 801(a)(3); ADULTERATION	The article appears to be held in a container containing a poisonous or deleterious substance which may render it injurious to health.
COSM COLOR	601(e), 801(a)(3); ADULTERATION	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to contain a color additive which is unsafe within the meaning of Section 721 (a) which renders it adulterated under Section 601(e).
COSMETIC	601(c), 801(a)(3); Adulteration	The article appears to be an ingredient in a cosmetic product and may have been prepared packed or held under insanitary conditions whereby it may have become contaminated with filth or rendered injurious to health.
COSMETLBLG	5(c)(3)(A); 801(a)(3) Misbranding	It appears the label does not bear the common or usual name of the cosmetic.
COSMETLBLG	5(c)(3)(B); 801(a)(3) Misbranding	It appears that the cosmetic consists of two or more ingredients and the label does not list the common or usual name of each ingredient.
COSM MISB	602(a) & 801(a)(3); MISBRANDING	The cosmetic's labeling appears to be false or misleading within the meaning of Section 201(n).
COSM MISB2	602(a) & 801(a)(3); MISBRANDING	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears that its labeling is false or misleading in any particular [Misbranding, Section 602 (a)].
COUMARIN	402(a)(1), 801(a)(3), Adulteration	The article appears to bear or contain Coumarin, a poisonous or deleterious substance, which may render it injurious to health.

CSTIC LBLG	602(a) and/or (b), and/or (c), 801(a)(3); MISBRANDING	The labeling appears to fail to comply with cosmetic labeling requirements of Section 602(a), and/or (b), and/or (c), and as identified by 21 C.F.R. Part 701.
CYCLAMATE	402(a)(2)(C); 801(a)(3)	The article appears to bear or contain cyclamate, an unsafe food additive within the meaning of Section 409
DANGEROUS	502(j), 801(a)(3); MISBRANDING	The article appears to be dangerous to health when used in the dosage or manner, or with the frequency or duration, prescribed, recommended, or suggested in the labeling thereof.
DE IMP GMP	801(a)(1); NON CONFORMING MANUFACTURING PRACTICES	The methods used in, or the facilities or controls used for the manufacture, packing, storage or installation do not conform to the requirements under section 520(f).
DE/RX KIT	801(d)(1),(2); IMPORTATION RESTRICTED	The article appears to be a combination medical device/ prescription drug kit for which the prescription drug component was manufactured in the U.S., is offered for import by other than the manufacturer, and reimportation does not appear to have been authorized by the Secretary for use in a medical emergency.
DEVGMPs	520(f); 801(a)(1)	The article appears to be a device for which the methods, facilities, or controls used in, or the facilities or controls used for, its manufacture, packing, storage or installation do not conform to the requirements of Sec. 520(f) and any applicable variance under Sec. 520(f)(2).
DEVICEGMPs	501(h), 801(a)(1); ADULTERATION	The methods, facilities, or controls used for the article's manufacture, packing, storage, or installation do not conform with applicable requirements under section 520(f)(1) or a condition prescribed by an order under section 520(f)(2).
DIETARY	403(j), 801(a)(3); MISBRANDING	The article purports to be or is represented for special dietary uses and its label does not appear to bear the nutritional information required by regulation.
DIETARYLBL	403(s)(2)(B), 801(a)(3), misbranded	The label/labeling of the dietary supplement fails to identify the product by using the term "dietary supplement".
DIET INGRE	402(a)(3), 801(a)(3); Adulteration	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be for use as an ingredient in a dietary supplement and appears to be or may be otherwise unfit for food.
DIOXIN	402(a)(1),402(a)(2)(A), 402(a)(2)(C)(i),801(a)(3)-Adulterated	The article appears to bear or contain dioxins and/or PCB compounds, poisonous or deleterious substances and/or unapproved food additives which may render it injurious to health.

DIRECTIONS	502(f)(1), 801(a)(3); MISBRANDING	The article appears to lack adequate directions for use.
DIRSEXMPT	502(f)(1), 801(a)(3); MISBRANDING	The article appears to lack adequate directions for use, and the article does not appear to be exempt from such requirements.
DISEASED	402(a)(5), 801(a)(3); ADULTERATION	The food appears to be, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter.
DRG REF EI	801(a)(3), 501(j); ADULTERATION	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the article of drug appears to be adulterated under Section 501(j) because it has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection.
DR PACKGNG	502(i) (1), 801(a)(3); MISBRANDING	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the article appears to be a drug and its container is so made, formed, or filled as to be misleading
DR QUALITC	501(c), 801(a)(3); ADULTERATION	The drug appears to be represented as not being recognized in an official compendium and appears its strength differs from or its quality or purity falls below, that which it purports or is represented to possess.
DR QUALITY	501(b), 801(a)(3); ADULTERATION	The article appears to be represented as a drug the name of which is recognized in an official compendium and its strength appears to differ from or its quality or purity appear to fall below the standards set forth in such compendium.
DRUG COLOR	502(m), 801(a)(3); MISBRANDING	The article appears to be a color additive the intended use of which is for the purpose of coloring only, and its packaging and labeling do not conform to regulations issued under section 721.
DRUG GMPS	501(a)(2)(B), 801(a)(3); ADULTERATION	It appears that the methods used in, or the facilities or controls used for, manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practices.
DRUG NAME	502(e)(1); 801(a)(3); Misbranding	The article appears to be a drug and fails to bear the proprietary or established name and/or name and quantity of each active ingredient.
DULCIN	402(a)(2)(C); 801(a)(3)	The article appears to bear or contain dulcin, an unsafe food additive within the meaning of Section 409

DV NAME	502(e)(2); 801(a)(3); Misbranding	The article appears to be a device and its labeling fails to bear the proprietary or established name.
DV QUALITY	501(c); 801(a)(3) Adulteration	The article appears to be a device whose quality falls below that which it purports or is represented to possess.
E COLI 157	402(a)(1), 801(a)(3); ADULTERATION	The article appears to contain E. coli O157:H7 (EHEC), a poisonous and deleterious substance which may render it injurious to health.
ELTNOCERT	534, 536(a)	It appears that the article is an electronic product subject to a performance standard, and does not have affixed to it a certification in the form of a label or tag in conformity with section 534(h).
EPHEDALK	801(a)(3), 402(f)(1); ADULTERATION	The product is subject to refusal of admission pursuant to Section 801(a)(3) in that it is a dietary supplement or a dietary ingredient that appears to contain ephedrine alkaloids, which presents an unreasonable risk of illness or injury under the conditions of use recommended or suggested in the labeling, or if no conditions of use are suggested in the labeling, under ordinary conditions of use.
EXCESS SUL	402(a)(1), 801(a)(3); ADULTERATION	The article appears to contain excessive sulfites, a poisonous and deleterious substance which may render it injurious to health.
EXPIRED	501(c); 801(a)(3) Adulteration	the product strength differs from, or its purity or quality falls below, that which it purports or is represented to possess in that it is past its labeled expiration date.
FAILS STD	501(e), 801(a)(3); ADULTERATION	The article appears to be a device which is subject to a performance standard established under Section 514 and does not appear to be in all respects in conformity with such standard.
FALSE	403(a)(1), 801(a)(3); MISBRANDING	The labeling appears to be false and misleading in any particular.
FALSE	502(a), 801(a)(3); MISBRANDING	The labeling for this article appears to be false or misleading
FALSECAT	403(t), 801(a)(3)	The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be misbranded because it purports to be or is represented as catfish but is not a fish classified within the family Ictaluridae.
FALSERXLBL	503(b)(4)(B), 801(a)(3)	The article is subject to refusal of admission pursuant section 801(a)(3) of the FD&CA in that it appears to be misbranded as defined in section 503(b)(4)(B) of the FD&C Act. The labeling falsely bears the symbol "RX Only".

FDF4APIGMP	501(a)(2)(B), 801(a)(3); ADULTERATION	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the methods and controls used in its manufacture and control do not appear to conform to current good manufacturing practices within the meaning of Section 501(a)(2)(B). This finished dosage form drug is made using an Active Pharmaceutical Ingredient from a facility that has been found non-compliant with current Good Manufacturing Practice (see Import Alert 66-40; <a href="http://www.accessdata.fda.gov/cms_ia/importalert_189.html">http://www.accessdata.fda.gov/cms_ia/importalert_189.html</a> ). You may submit testimony to provide evidence to overcome the appearance of adulteration. The API source for this finished dosage form drug is:
FEED & NAD	501(a)(6), 801(a)(3); ADULTERATION	The article appears to be an animal feed bearing or containing a new animal drug, and such animal feed is unsafe within the meaning of section 512.
FILTH	501(a)(1)Adulteration	The article is subject to refusal of admission pursuant to section 801(a)(3) of the FFD&CA in that the article contains potentially hazardous, or otherwise objectionable in light of intended use, microbial adulteration and therefore consists in part of a filthy substance
FILTH	601(b), 801(a)(3); ADULTERATION	The cosmetic appears to consist in whole or in part of any filthy, putrid, or decomposed substance.
FILTHY	402(a)(3), 801(a)(3); ADULTERATION	The article appears to consist in whole or in part of a filthy, putrid, or decomposed substance or be otherwise unfit for food.
FLAVR LBLG	403(k), 801(a)(3); MISBRANDING	The article appears to contain an artificial flavoring and it fails to bear labeling stating that fact.
FLUOROCARB	402(a)(2)(A), 801(a)(3); ADULTERATION	The article appears to contain chlorofluorocarbons in violation of 21 CFR 2.125.
FLUOROCARB	501(a)(5), 801(a)(3); ADULTERATION	The article appears to be a new animal drug containing chlorofluorocarbons in violation of 21 CFR 2.125.
FLUOROCARB	601(a), 801(a)(3); ADULTERATION	The article appears to contain chlorofluorocarbons in violation of 21 CFR Part 2.125.
FORBIDDEN	801(a)(2); FORBIDDEN OR RESTRICTED IN SALE	The article appears to be forbidden or restricted in sale in the country in which it was produced or from which it was exported.
FOREIGN OB	402(a)(3), 801(a)(3); ADULTERATION	The article appears to consist in whole or in part of a filthy, putrid, or decomposed substance, or is otherwise unfit for food in that it appears to contain foreign objects.

FRNMFGREG	502(o), 801(a)(3); MISBRANDING	The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be misbranded as defined in section 502(o) of the FD&CA. It appears that it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the Act. [Misbranding, Section 502(o), 801(a)(3)].
GINSENG	402(a)(2)(C), 801(a)(3); ADULTERATION	The article appears to bear or contain "Ginseng", a food additive which is unsafe within the meaning of Section 409.
HEALTH C	801(a)(3); 403(r)(1)(A)/ (B) misbranding	The article appears to be misbranded in that the label or labeling bears an unauthorized nutrient content/health claim.
HELD INSAN	601(c), 801(a)(3); ADULTERATION	The cosmetic appears to have been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.
HEPATITISA	Section 801(a)(3), 402 (a)(1); ADULTERATION	The article appears to contain Hepatitis A Virus, a poisonous or deleterious substance which may render it injurious to health.
HISTAMINE	402(a)(1), 801(a)(3); Adulteration	The article appears to bear or contain histamine, a poisonous and deleterious substance in such quantity as ordinarily renders it injurious to health.
HOLES	501(c); 801(a)(3) Adulteration	The quality of the article falls below that which it purports or is represented to possess, in that the devices contain defects/holes.
IMBED OBJT	402(d)(1), 801(a)(3); ADULTERATION	The article appears to be a confectionary that has partially or completely imbedded therein any nonnutritive object.
IMITATION	403(c), 801(a)(3); MISBRANDING	The article appears to be an imitation of another food, and the label does not bear in type of uniform size and prominence, the word "imitation" and immediately thereafter, the name of the food imitated.
IMITN DR	502(i) (2), 801(a)(3); MISBRANDING	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be an imitation of another drug. The article resembles:
IMPTRHACCP	801(a)(3) , 402(a)(4) Adulteration	The food appears to have been prepared, packed or held under insanitary conditions, or may have become injurious to health, due to the failure of the importer to provide verification of compliance pursuant to 21 CFR 123.12(d).

INADQ PAST	402(a)(4), 801(a)(3); ADULTERATION	The article is subject to refusal of admission pursuant to section 801 (a)(1) in that it appears to have been manufactured or processed under insanitary conditions which may result in unpasteurized or inadequately pasteurized product [Adulteration,402(a)(4)].
INCONSPICU	403(f), 801(a)(3); MISBRANDING	Information required by the Act to be on the label or labeling does not appear to be conspicuous enough as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
INCONSPICU	502(c), 801(a)(3); MISBRANDING	Information required by the Act to be on the label or labeling does not appear to be conspicuous enough as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
INGRED FIL	402(a)(4), 801(a)(3); Adulteration	The article appears to be an ingredient in a dietary supplement and may have been prepared packed or held under insanitary conditions whereby it may have become contaminated with filth or rendered injurious to health.
INSAN BSE	402(a)(4), 801(a)(3); Adulteration	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to have been prepared, packed or held under insanitary conditions whereby it may have been rendered injurious to health.
INSANITARY	402(a)(4), 801(a)(3); ADULTERATION	The article appears to have been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.
INSANITARY	501(a)(2)(A), 801(a)(3); ADULTERATION	The article appears to have been prepared, packed or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.
INVDEVICE	501(i), 801(a)(3); ADULTERATION	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a device for investigational use for which no exemption has been granted as prescribed by Section 520(g)
JUICE %	403(i)(2), 801(a)(3); MISBRANDING	It appears the food is a beverage containing vegetable or fruit juice and does not bear a statement on the label in appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained therein.
JUICEHACCP	801(a)(3);402(a)(4)	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to have been prepared, packed, or held under insanitary conditions, or it may be injurious to health, due to failure of the foreign processor to comply with 21 CFR 120 [Adulteration, 402(a)(4)].
LABELING	Section 4(a); 801(a)(3) Misbranding	The article appears in violation of FPLA because of its placement, form and/or contents statement.

LACK NOTIF	301(s)	Adulterated, 801(a)(3), lack of documentation establishing that the infant formula meets all notification conditions required by 412(c) or 412(d), Prohibited Act, Section 301(s).
LACKS FIRM	403(e)(1), 801(a)(3); MISBRANDING	The food is in package form and appears to not bear a label containing the name and place of business of the manufacturer, packer, or distributor.
LACKS FIRM	502(b)(1), 801(a)(3); MISBRANDING	The article is in package form and appears to not bear a label containing the name and place of business of the manufacturer, packer, or distributor.
LACKS N/C	403(e)(2), 801(a)(3); MISBRANDING	The food is in package form and appears to not have a label containing an accurate statement of the quantity of the contents in terms of weight, measure or numerical count and no variations or exemptions have been prescribed by regulations.
LACKS N/C	502(b)(2), 801(a)(3); MISBRANDING	The article is in package form and appears to not have a label containing an accurate statement of the quantity of the contents in terms of weight, measure or numerical count and no variations or exemptions have been prescribed by regs.
LBLG ADVER	502(a), 201(n) and 801(a)(3) Misbranding	The art appr misbranded because its lbg is misledg namely it fails to reveal facts (non-sterility) that are material w/ respect to consequences frm the use of the art accordg to lbg or advertisg or undercondtns of customary or usual use
LBL STEEL	502(a); 801(a)(3); Misbranding	The labeling for this article appears to be false or misleading: labeling suggests it is composed of stainless steel, but it doesn't meet standard requirements for the appropriate type of stainless steel.
LEAK/SWELL	402(a)(3), 801(a)(3); ADULTERATION	The article appears to be held in swollen containers or contains micro leaks.
LENS CERT	502(a), 801(a)(3); MISBRANDING	The lenses are declared by accompanying certificate to meet the requirements for impact-resistant lenses in 21 CFR 801.410 but does not appear to be impact-resistant.
LISTERIA	402(a)(1), 801(a)(3); ADULTERATION	The article appears to contain Listeria, a poisonous and deleterious substance which may render it injurious to health.
LIST INGRE	403(i)(2), 801(a)(3); MISBRANDING	It appears the food is fabricated from two or more ingredients and the label does not list the common or usual name of each ingredient.
MELAMINE	402(a)(2)(C)(i), 801(a)(3); ADULTERATION	The article appears to bear or contain a food additive, namely melamine and/or a melamine analog, that is unsafe within the meaning of section 409 [Adulteration, section 402(a)(2)(C)(i)].

MFRHACCP	402(a)(4), 801(a)(3)	The product appears to have been prepared, packed, or held under insanitary conditions, or it may be injurious to health, due to failure of the foreign processor to comply with 21 CFR 123.
MFR INJ	402(a)(4),801(a)(3); ADULTERATION	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act (the Act) in that such article appears to have been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health. [Adulteration, Section 402(a)(4) of the Act]
MFR INSAN	801(a)(1); INSANITARY MANUFACTURING, PROCESSING OR PACKING	The article is subject to refusal of admission pursuant to section 801(a)(1) in that the article appears to have been manufactured, processed, or packed under insanitary conditions.
NCONTACTS	403(y), 801(2)(3); Misbranding	The product is a dietary supplement that is marketed in the United States and appears to not have a domestic address or domestic phone number through which the responsible person may receive a report of a serious adverse event.
NEEDS ACID	402(a)(4), 801(a)(3); ADULTERATION	The food appears to have been prepared, packed, or held under insanitary conditions, or it may have been rendered injurious to health due to inadequate acidification.
NEEDS FCE	402(a)(4), 801(a)(3); ADULTERATION	It appears the manufacturer is not registered as a low acid canned food or acidified food manufacturer pursuant to 21 CFR 108.25(c)(1) or 108.35(c)(1).
NEW VET DR	501(a)(5), 801(a)(3); ADULTERATION	The article appears to be a new animal drug which is unsafe within the meaning of Section 512(a) in that there is not in effect an approval of an applications filed with respect to its intended use or uses.
NITROFURAN	402(a)(2)(C)(i), 801(a) (3); Adulteration	The article is subject to refusal of admission in that it appears to bear or contain a food additive, namely nitrofurans, that is unsafe.
NO 510(K)	801(a)(3); 502(o) Misbranding	It appears that a notice or other information respecting the device was not provided to FDA, as required by Section 510 (k) and the device was not found to be substantially equivalent to a predicate device.
NOCONTCODE	402(a)(4), 801(a)(3); ADULTERATION	The low acid or acidified food appears to have been prepared, packed, or held under insanitary conditions, or it may be injurious to health, due to failure to mark with a permanent container code pursuant to 21 CFR 113.60(c) or 114.80(b).
NO ENGLISH	403(f), 801(a)(3); MISBRANDING	Required label or labeling appears to not be in English per 21 CFR 101.15(c).

NO ENGLISH	502(c); 801(a) (3);Misbranding	Required label or labeling appears to not be in English in violation of 21 C.F.R. 801.15(c)(1)
NO ENGLISH	502(c); 801(a) (3) ;MISBRANDING	Required label or labeling appears to not be in English in violation of 21 C.F.R. 201.15(c)(1).
NO LICENSE	502(f)(1), 801(a)(3); MISBRANDING & PHS BIOL. ACT 351	The article appears to be a biological product not manufactured at an establishment holding an unsuspended and unrevoked license issued under the Public Health Service Act, Biological Products section 351.
NONCOMELT	534, 536(a)	It appears that the article is an electronic product which fails to comply with one or more applicable standards prescribed under section 534.
NONNUT SUB	402(d)(3), 801(a)(3); ADULTERATION	The article appears to be confectionery and it bears or contains a nonnutritive substance.
NONRSP-PRC	402(a)(4), 801(a)(3); ADULTERATION	The article appears to have been prepared or packed under insanitary conditions whereby it may have been rendered injurious to health due to inadequate processing in that the scheduled process filed by the manufacturer pursuant to 21 CFR 108.35(c)(2) appears to be inadequate to protect the public health.
NONRSP-VER	402(a)(4), 801(a)(3); ADULTERATION	The article appears to have been prepared or packed under insanitary conditions whereby it may have been rendered injurious to health due to inadequate processing in that the scheduled process filed by the manufacturer for this thermally processed low acid food packaged in a hermetically sealed container pursuant to 21 CFR 108.35 (c)(2) appears to be inadequate to protect the public health.
NON STD	536(a),(b); NON STANDARD	It appears that the article fails to comply with applicable standards prescribed under section 534.
NONSTEEL	502(a) and/or 502(f)(1); Misbranding	Labeling appears false or misleading or fails to bear adequate directions for use,because the article appears to be misrepresented as a disposable single use instrument when it is intended for use as a stainless steel multi-use instrument.
NO PERMIT	1, 2; PROHIBITION WITHOUT PERMIT	The article of milk or cream is not accompanied by a valid import milk permit, as required by the Federal Import Milk Act (21 U.S.C. 141-149).
NO PMA	501(f)(1)(B), 801(a)(3); ADULTERATION	The article appears to be a class III device without an approved application for premarket approval pursuant to section 515(a).

NO PMA/PDP	501(f)(1)(A); 801(a)(3); ADULTERATION	The article appears to be a class III dev.w/o an approved applic. for premarket approval, and/or a notice of completion of product development protocol filed per section 515(b) or exempt per sect.520(g)(1). [Adulteration, Section 501(f)(1)(A)]
NO PROCESS	402(a)(4), 801(a)(3); ADULTERATION	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the manufacturer's failure to file a scheduled process demonstrates that the product is not being manufactured under the mandatory provisions of 21 CFR Part 108 and therefore appears to have been manufactured, processed, or packed, under insanitary conditions whereby it may have been rendered injurious to health.
NO REGISTR	536(a); Failure to file initial report	The article appears to be an electronic product that does not comply with an applicable standard as prescribed by Section 534 because no reporting has been provided as required by Section 537(b).
NO TAG	536(a),(b); NOT CERTIFIED	It appears that the article does not have affixed to it a certification in the form of a label or tag in conformity with section 534(h).
NOT IMPACT	501(c), 801(a)(3); ADULTERATION	The article appears to not have impact-resistant lenses in accordance with 21 CFR 801.410.
NOT LISTED	502(o), 801(a)(3); MISBRANDING	It appears the drug or device is not included in a list required by Section 510(j), or a notice or other information respecting it was not provided as required by section 510(j) or 510(k).
N-RX INACT	502(e)(1); 801(a)(3); Misbranding	The article appears to be a nonprescription drug and fails to bear the established name of each inactive ingredient in alphabetical order on the outside container of the retail package.
NUTR DEF	412(a)(1), 801(a)(3); Adulterated	the infant formula appears to adulterated in that it does not provide the nutrients required by 21 CFR 107.100
NUTRIT LBL	403(q); 801(a)(3); Misbranding	The article appears to be misbranded in that the label or labeling fails to bear the required nutrition information.
NUTR UNIT	403(f), 801(a)(3); MISBRANDED	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the infant formula appears to be misbranded within the meaning of Section 403 in that the labeling fails to use the proper units to declare the nutrients as specified in 21 CFR 107.10 [Misbranded, Section 403(f)].
OFF ODOR	402(a)(3), 801(a)(3); ADULTERATION	The article appears to consist in whole or in part of a filthy, putrid, or decomposed substance or be otherwise unfit for food. Contains an off odor.

OMITTED	402(b)(1), 801(a)(3); ADULTERATION	It appears that a valuable constituent of the article has been in whole or in part omitted or abstracted from the article.
OPTION ING	403(g)(2), 801(a)(3); MISBRANDING	It appears to be a food for which a definition and standard of identity have been prescribed by regulations under section 401 and appears to not be labelled with the common names of the optional ingredients specified therein.
OTHER DRUG	502(i) (3), 801(a)(3); MISBRANDING	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the article is a drug and if it is offered for sale under the name of another drug.
PATULIN	402(a)(1), 801(a)(3); ADULTERATION	The article appears to contain patulin, a poisonous and deleterious substance which may render it injurious to health.
PB-FOOD	402(a)(1); 801(a)(3); Adulteration	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to contain a poisonous or deleterious substance, lead, which may render it injurious to health.
PERSONALRX	502(a) & (f)(1), 801(a) (3); MISBRANDING	The article appears to be a drug which requires a prescription from your doctor.
PESTICIDE	402(a)(2)(B), 801(a)(3); ADULTERATION	The article appears to be a raw agricultural commodity that bears or contains a pesticide chemical which is unsafe within the meaning of Section 408(a).
PESTICIDE2	402(a)(2)(B); 801(a)(3); ADULTERATION	The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be adulterated because it contains a pesticide chemical, which is in violation of section 402(a)(2)(B). Contains:
POISONOUS	402(a)(1), 801(a)(3); ADULTERATION	The article appears to contain a poisonous or deleterious substance which may render it injurious to health.
POISONOUS	601(a), 801(a)(3); ADULTERATION	The cosmetic appears to bear or contain a poisonous or deleterious substance which may render it injurious to users under the conditions prescribed in the labeling thereof, or, under such conditions of use as are customary or usual.
POISON PKG	502(p), 801(a)(3); MISBRANDING	The article appears to be a drug and its packaging and labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.
POSS N/STR	501(a)(1); 801(a)(3) ADULTERATION	The article appears to consist in whole or in part of any filthy, putrid, or decomposed substance, namely, potentially infectious organisms
PRESRV LBL	403(k), 801(a)(3); MISBRANDING	The article appears to contain a chemical preservative and it fails to bear labeling stating that fact including its function.

RADIONUC	402(a)(1); 801(a)(3); Adulteration	Article appears to contain the radionuclide, Cesium-137, a poisonous and deleterious substance which may render it injurious to health.
RECORDS	502(t), 801(a)(3); MISBRANDING	The article appears to be a device and the requirements under 518 or to furnish any material or information required by or under section 519 respecting a device were not met.
REDUCED	501(d)(1), 801(a)(3); ADULTERATION	It appears to be a drug that a substance has been mixed or packed with so as to reduce its strength.
REFUSE EI	801(a)(1); INSANITARY MANUFACTURING, PROCESSING OR PACKING	The article is subject to refusal of admission pursuant to Section 801(a)(1) in that the article appears to have been manufactured, processed, or packed under insanitary conditions.
REGISTERED	502(o), 801(a)(3); MISBRANDING	It appears the device is subject to listing under 510(j) and the initial distributor has not registered as required by 21 CFR 807.20 (a)(5).
RXCOMPOUND	503(b)(4)(A) & 502(c), 801(a)(3); MISBRANDING	the labeling fails to bear, at a minimum, the symbol "Rx only."
RX DEVICE	502(a),(f)(1), 801(a)(3); MISBRANDING	The article appears to be a prescription device without a prescription device legend as required by 21 CFR 801.109.
RXLABEL	503(b)(4)(A), 801(a)(3); MISBRANDING	The labeling fails to bear, at a minimum, the symbol "RX Only".
RX LEGEND	502(a) & (f)(1), 801(a) (3); MISBRANDING	The article appears to be a prescription drug without a prescription drug legend as required by Section 503(b)(4).
RXPERSONAL	502(a), 502(f)(1), 801(a) (3), MISBRANDING	The article appears to be a device which requires a prescription from your doctor.
RXVETLACK	503(f)(4), 801(a)(3)	The article appears to be a drug which requires a prescription from your doctor.
RXVETLACK2	503(f)(4), 801(a)(3)	The article appears to be a veterinary drug which requires but lacks the "Caution" statement specified at Sec. 503(f)(4).
SACCHARLBL	403(i), 801(a)(3); Misbranding	The article appears to contain Saccharin, a non-nutritive sweetener, and its label or labeling fails to list it as an added ingredient.
SALMONELLA	402(a)(1), 801(a)(3); ADULTERATION	The article appears to contain Salmonella, a poisonous and deleterious substance which may render it injurious to health.

SBGINSENG	801(a)(3); 403(u) Misbranding	The article is subject to refusal of admission in that it appears to be Misbranded because it or its ingredients purport to be or are represented as Ginseng, but are not an herb or herbal ingredient derived from a plant classified within the genus Panax.
SHIGELLA	402(a)(1), 801(a)(3); ADULTERATION	The article appears to contain Shigella, a poisonous and deleterious substance which may render it injurious to health.
SOAKED/WET	402(a)(4), 801(a)(3); ADULTERATION	The article appears to have been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health in that it appears to been held in water.
STAINSTEEL	501(c); 801(a)(3) Adulteration	The article appears to be a device whose quality falls below that which it purports or is represented to possess, in that instrument is represented as stainless steel but does not meet requirements for such steel for surgical instruments.
STARANISE	402(a)(2)(C)(i), 801(a) (3), Adulteration	The article appears to bear or contain a food additive, Japanese star anise, that is unsafe within the meaning of section 409.
STD FILL	403(h)(2), 801(a)(3); MISBRANDING	The article appears to be represented as a food for which a standard of fill of container has been prescribed by regulations as provided by section 401 and it appears it falls below the standard of fill and its label does not so indicate.
STD IDENT	403(g)(1), 801(a)(3); MISBRANDING	The food appears to be represented as a food for which a definition and standard of identity have been prescribed by regulations as provided by section 401 and the food does not appear to conform to such definition and standard.
STD LABEL	502(s), 801(a)(3); MISBRANDING	The article appears to not bear labeling prescribed by the performance standard established under section 514.
STD NAME	403(g)(2), 801(a)(3); MISBRANDING	It appears to be a food for which a definition and standard of identity have been prescribed by regulations under section 401 and appears to not be labelled with the name specified in the definition and standard.
STD QUALIT	403(h)(1), 801(a)(3); MISBRANDING	The article appears to be represented as a food for which a standard of quality has been prescribed by regulation as provided by Sec. 401 and it appears its quality falls below such standard and its label does not so indicate.
STERILITY	501(a)(1), 801(a)(3); ADULTERATION	The article appears to consist in whole or in part of any filthy, putrid, or decomposed substance.

STERILITY	501(a)(2)(A), 801(a)(3); ADULTERATION	The article appears to have been prepared, packed or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.
SUBSTITUTE	402(b)(2), 801(a)(3); ADULTERATION	It appears that a substance has been substituted wholly or in part for one or more of the article's ingredients.
SUBSTITUTE	501(d)(2), 801(a)(3); ADULTERATION	It appears to be a drug that a substance has been substituted wholly or in part.
SULFITELBL	403(a)(1), 801(a) (3); MISBRANDING	The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be misbranded because 1) it appears to contain sulfites but the label fails to declare the presence of sulfites, a fact material to sulfite-sensitive individuals who must avoid the ingredient due to potential health consequences from its consumption [Misbranded, 403(a)(1)], and 2) it appears the food is fabricated from two or more ingredients and the label does not list the common or usual name of each ingredient [Misbranded, 403(i)(2)].
SUPPL GMP	402(g)(1), Adulteration, 801(a)(3), Adulteration	The article appears to be a dietary supplement and it has been prepared, packed, or held under conditions that do not meet current good manufacturing practice regulations.
TAMPERING	501(a)(2)(B), 801(a)(3); ADULTERATION	It appears that the packing does not conform with current good manufacturing practices under 21 CFR 211.132 for tamper-resistant packaging.
TISSUE	361	This human cell, tissue, and cellular and tissue-based product is in violation of Section 361 of the Public Health Service Act.
TPFDA1LBLG	903(a)(1); 801(a)(3); 301(tt)(1); MISBRANDING	This article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act because it is a tobacco product that appears to be misbranded under section 903(a)(1) in that the label or labeling is false or misleading because it conveys that the product is approved by the FDA.
TPFDA2LBLG	903(a)(1); 801(a)(3); 301(tt)(2); MISBRANDING	This article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act because it is a tobacco product that appears to be misbranded under section 903(a)(1) in that the label or labeling is false or misleading because it conveys that the FDA deems the product to be safe for use by consumers.
TPFDA3LBLG	903(a)(1); 801(a)(3); 301(tt)(3); MISBRANDING	This article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act because it is a tobacco product that appears to be misbranded under 903(a)(1) in that the label or labeling is false or misleading because it conveys that the product is endorsed by the FDA for use by consumers.

TPFDA4ALBL	903(a)(1); 801(a)(3); 301(tt)(4)(A); MISBRANDING	This article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act because it is a tobacco product that appears to be misbranded under section 903(a)(1) in that the label or labeling is false or misleading because it conveys that the product is safe or less harmful by virtue of its regulation or inspection by the FDA.
TPFDA4BLBL	903(a)(1); 801(a)(3); 301(tt)(4)(B); MISBRANDING	This article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act because it is a tobacco product that appears to be misbranded under 903(a)(1) in that the label or labeling is false or misleading because it conveys that the product is safe or less harmful by virtue of its compliance with regulatory requirements set by the FDA.
TP FLAVOR	902(a)(5), 927(a)(1)(A), 801(a)(3); ADULTERATION	The article is subject to refusal of admission pursuant to section 801(a)(3) of the Act in that it purports to be or is represented as, a tobacco product which is subject to a tobacco product standard established under section 907, and the article (or its components) appears to contain, as a constituent or additive, an artificial or natural flavor or an herb or spice, that is a characterizing flavor of the tobacco product or tobacco smoke.
TPLACKFIRM	903(a)(2)(A); 801(a)(3); MISBRANDING	This article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act because it is a tobacco product in package form that appears to be misbranded under section 903(a)(2)(A) in that the label does not contain the name and place of business of the tobacco product manufacturer, packer or distributor.
TPLACKSNC	903(a)(2)(B); 801(a)(3); MISBRANDING	This article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act because it is a tobacco product in package form that appears to be misbranded under section 903(a)(2)(B) in that the label does not provide an accurate statement of the quantity of contents in terms of weight, measure or numerical count.
TPLBLFALSE	903(a)(1);801(a) (3);MISBRANDING	This article is subject to refusal of admission pursuant to section 801(a)(3) of the Act in that it is a smokeless tobacco product and it appears that its labeling is false or misleading because its package does not bear any of the warnings required by section 3 of the Comprehensive Smokeless Tobacco Education Act, as amended (i.e., it does not bear any of the following warnings: "WARNING: This product can cause mouth cancer." "WARNING: This product can cause gum disease and tooth loss." "WARNING: This product is not a safe alternative to cigarettes." "WARNING: Smokeless tobacco is addictive.")
TPLKDOMFOR	903(a)(2)(C); 801(a)(3); MISBRANDING	This article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act because it is a tobacco product in package form that appears to be misbranded under section 903(a)(2)(C) in that the label does not provide an accurate statement of the percentage of the tobacco used in the product that is domestically grown tobacco and the percentage foreign grown tobacco.

TPLKUSSLLB	903(a)(2)(D); 801(a)(3); MISBRANDING	This article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act because it is a tobacco product in package form that appears to be misbranded under section 903(a)(2)(D) in that the label does not provide the statement "sale only allowed in United States" and the tobacco product is not subject to any exemptions or variations.
TPNOHLDOCS	903(a)(10)(A); 801(a)(3) MISBRANDING	This article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act because it is a tobacco product that appears to be misbranded under section 903(a)(10)(A) in that documents related to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents(including smoke constituents), ingredients, components, and additives were not submitted as required under section 904(a)(4).
TP NO HPHC	903(a)(10)(A); 801(a)(3) MISBRANDING	This article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act because it is a tobacco product that appears to be misbranded under section 903(a)(10)(A) in that a listing of constituents, including smoke constituents, identified as harmful or potentially harmful to health in each tobacco product was not submitted as required under section 904(a)(3).
TP NO ING	903(a)(10)(A); 801(a)(3) MISBRANDING	This article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act because it is a tobacco product that appears to be misbranded under section 903(a)(10)(A) in that a list of all ingredients, including tobacco, substances, compounds, and additives that are added by the manufacturer to the tobacco, paper, filter, or part of each tobacco product by brand and by quantity in each brand and sub-brand was not submitted as required under section 904(a)(1).
TP NO PMTA	801(a)(3);902(6)(A);ADULTERATION	This article is subject to refusal of admission pursuant to section 801(a)(3)of the Act because it is a tobacco product that appears to be adulterated under section 902(6)(A) in that it requires premarket review under section 910(a) and does not have an order in effect under section 910(c)(1)(A)(i). [Adulteration: Section 902(6)(A) FD&C Act]
TP NO SE	801(a)(3);903(a)(6);MISBRANDING	This article is subject to refusal of admission pursuant to section 801(a)(3) of the Act because it is a tobacco product which appears to be misbranded under section 903(a)(6)in that a notice or other information respecting it was not provided as required by section 905(j). [Misbranding: Section 903(a)(6)FD&C Act]

TPNOWRNLBL	903(a)(8)(B)(i);801(a)(3);MISBRANDING	This article is subject to refusal of admission pursuant to section 801(a)(3) of the Act in that it is a smokeless tobacco product and it appears that its package label does not include a brief statement of the relevant warnings (i.e., one of the following warnings required by section 3 of the Comprehensive Smokeless Tobacco Education Act as amended: "WARNING: This product can cause mouth cancer." "WARNING: This product can cause gum disease and tooth loss." "WARNING: This product is not a safe alternative to cigarettes." "WARNING: Smokeless tobacco is addictive.")
TP USERFEE	902(4);801(a)(3); ADULTERATION	This article is subject to refusal of admission pursuant to Section 801(a)(3) of the FD&C Act in that the tobacco product appears to be adulterated under Section 902(4) because the importer of the tobacco product failed to pay a user fee assessed to such importer pursuant to Section 919 by the date specified in Section 919 or by the 30th day after final agency action on a resolution of any dispute as to the amount of the fee.
TP VIOL911	902(8); 801(a)(3), Adulteration	The article is subject to refusal of admission pursuant to section 801(a)(3) of the Act in that it appears to be a tobacco product in violation of section 911 of the Act. [Adulteration: Section 902(8)]
TRANSFAT	403(q), 801(a)(3); MISBRANDING	The product is misbranded under Section 403(q) because the nutrition label does not provide all of the information required by 21 CFR 101.9(c); specifically, the label does not bear the amount of trans fat [21 CFR 101.9(c)(2)(ii)].
UNAPPROVED	505(a), 801(a)(3); UNAPPROVED NEW DRUG	The article appears to be a new drug without an approved new drug application.
UNDER PRC	402(a)(4), 801(a)(3); ADULTERATION	The article appears to have inadequate processing in having been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health.
UNFIT4FOOD	402(a)(3), 801(a)(3); ADULTERATION	The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be unfit for food [Adulteration, 402(a)(3)]
UNSAFE ADD	402(a)(2)(C)(i), 801(a)(3); ADULTERATION	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to contain an unsafe food additive within the meaning of Section 409 [Adulteration, Section 402(a)(2)(C)]. It contains:
UNSAFE COL	402(c), 801(a)(3); ADULTERATION	The article appears to be, or to bear or contain a color additive which is unsafe within the meaning of Section 721 (a).

UNSAFE COL	501(a)(4)(B), 801(a)(3); ADULTERATION	The article appears to be a color additive for the purposes of coloring only in or on drugs or devices, and is unsafe within the meaning of Section 721(a).
UNSAFE SUB	402(a)(2)(A), 801(a)(3); ADULTERATION	The article appears to bear or contain a substance which is unsafe within the meaning of Section 406.
UNSFDIETLB	402(f)(1)(A), 801(a)(3) Adulteration	The article appears to be a dietary supplement or contain a dietary ingredient that presents a significant or unreasonable risk of illness or injury under the conditions of use set out in the labeling or, if none are set out in the labeling, under customary conditions of use.
UNSFDIETSP	402(f)(1)(B), 801(a)(3) Adulteration	The article appears to be a dietary supplement or ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.
UNSFDIETUS	402(f)(1)(D), 801(a)(3) Adulteration	The article is or contains a dietary supplement that renders it adulterated under paragraph (a)(1) under conditions of use recommended or suggested in the labeling of such dietary supplement.
USUAL NAME	403(i)(1), 801(a)(3); MISBRANDING	It appears that the label does not bear the common or usual name of the food.
VETDRUGRES	402(a)(2)(C)(ii); 801(a) (3); ADULTERATION	The article appears to contain a new animal drug (or conversion product thereof) that is unsafe within the meaning of section 512. Product contains
VET LEGEND	502(a) & (f)(1), 801(a) (3); MISBRANDING	The article appears to be a veterinary drug without the "Caution" statement as required by Section 503(f)(4).
VIBRIO	402(a)(1), 801(a)(3); ADULTERATION	The article appears to contain Vibrio Cholerae, a poisonous and deleterious substance which may render it injurious to health.
VITAMN LBL	403(a)(2), 801(a)(3); MISBRANDING	The food appears to be subject to section 411 and its advertising is false or misleading in a material respect or its labeling is in violation of section 411(b)(2).
WARNINGS	502(f)(2), 801(a)(3); MISBRANDING	It appears to lack adequate warning against use in a pathological condition or by children where it may be dangerous to health or against an unsafe dose, method, administering duration, application, in manner/form, to protect users.
WRONG IDEN	403(b), 801(a)(3); MISBRANDING	The article appears to be offered for sale under the name of another food.

YELLOW #5

402(c), 403(m), 801(a)  
(3); ADULTERATION,  
MISBRANDING

The food appears to bear or contain the color additive FD & C Yellow No. 5, which is not declared on the label per 21 CFR 74.705(a)(c) under section 721.