

# FDA shipment refusal codes

ASC_ID	CHRG_CODE	CHRG_TXTMNT_TEXT	SCFN_NAME
9	SALMONELLA-9	<b>The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to contain Salmonella, a poisonous and deleterious substance which may render it injurious to health.</b>	<b>402(a)(1), 801(a)(3); ADULTERATION</b>
11	UNSAFE COL-11	The article appears to be, or to bear or contain a color additive which is unsafe within the meaning of Section 721(a).	402(c), 801(a)(3); ADULTERATION
15	DIRECTION35-16	The article is subject to refusal of admission pursuant to section 801(a)(3) in that it is a device whose label appears to not bear adequate directions for use.	502(f)(1), 801(a)(3); MISBRANDING
27	DRUG GMP5-27	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the methods used in and controls used for the manufacture, processing, packing, or holding of drugs and other products do not appear to conform to current good manufacturing practices within the meaning of Section 501(a)(2)(B).	501(a)(2)(B), 801(a)(3); ADULTERATION
47	NON STD-47	The article is subject to refusal of admission pursuant to section 536(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) in that it appears to be an electronic product offered for importation into the United States which fails to comply with an applicable standard prescribed pursuant to section 534 of the FDCA.	536(a)(b); NON STANDARD
48	NEEDS ACID-48	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 become contaminated with filth, or whereby it may have been rendered injurious to health due to inadequate acidification.	402(a)(4), 801(a)(3); ADULTERATION
55	OMITTED-55	The article is subject to refusal of admission pursuant Section 801(a)(3) of the FD&C Act in that it appears that a viable constituent of the article has been in whole or in part omitted or abstracted from the article.	402(b)(1), 801(a)(3); ADULTERATION
62	NEEDS FCE-62	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).	402(a)(4), 801(a)(3); ADULTERATION
64	YELLOW US-64	The article appears to consist in whole or in part of a filthy, putrid, or decomposed substance as defined in section 502(b)(1) of the FD&C Act. It also appears to be a device whose label appears to not bear adequate directions for use.	502(b)(1), 801(a)(3); ADULTERATION, MISBRANDING
71	NO LICENSE-71	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act (FDCA) because it appears to be a biological product for which a biologics license is not in effect under the Public Health Service Act, Part F, Subpart 1-Biological Products, Section 351(a), and it is not the subject of an Investigator 801(a)(3), 505, 502(f)(1); UNAPPROVED, MISBRANDED & PHS ACT	801(a)(3), 505, 502(f)(1); UNAPPROVED, MISBRANDED & PHS ACT
72	NEW VET DR-72	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the Federal Food, Drug, and Cosmetic Act in that it appears to be a new animal drug that is unsafe within the meaning of Section 512(a) of the Federal Food, Drug, and Cosmetic Act as it is not the subject of an approved new animal drug application, conditionally approved	501(a)(5), 801(a)(3); ADULTERATION
73	DRUG COLOR-73	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.	502(m), 801(a)(3); MISBRANDING
74	GINSENG-74	The article appears to bear or contain "ginseng," a food additive which is unsafe within the meaning of Section 409.	402(a)(2)(C), 801(a)(3); ADULTERATION
75	UNAPPROVED-75	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 (NDA).	505(a), 801(a)(3); UNAPPROVED NEW DRUG
78	STERILITY-78	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 become contaminated with filth, or whereby it may have been rendered injurious to health.	501(a)(2)(A), 801(a)(3); ADULTERATION
82	RX LEGEND-82	The article appears to be a prescription drug without a prescription drug legend as required by Section 503(b)(4).	502(a) & (f)(1), 801(a)(3); MISBRANDING
83	NO PROCESS-83	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the manufacturer's failure	402(a)(4), 801(a)(3); ADULTERATION
84	RX DEVICE-84	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it is a prescription device that appears to not feature a prescription device legend as required by 21 CFR 801.109.	501(a)(f)(1), 801(a)(3); MISBRANDING
115	DR QUALITY-115	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that 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.	502(b), 801(a)(3); ADULTERATION
117	DANGEROUS-117	The article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it 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 therefor.	502(j), 801(a)(3); MISBRANDING
118	NOT LISTED-118	The article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it appears to be misbranded as defined in section 502(i) of the FD&C Act. Based on the information available to the FDA, it appears that the drug or device is not included in a list required by Section 510(j), or a notice or other information respecting	501(a)(2)(A), 801(a)(3); ADULTERATION
122	ANTIBIOTIC-122	The drug appears to purport, or represented as, being composed wholly or partly of an antibiotic and it does not appear to be from a batch with respect to which a certificate or release has been issued pursuant to section 507. REPEALED11/97	502(i), 801(a)(3); MISBRANDING
123	BANNED-123	The article appears to be a banned device.	501(g), 801(a)(3); ADULTERATION
126	FAILS STD-126	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.	501(e), 801(a)(3); ADULTERATION
152	SOAKED/WET-152	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 be held in water.	402(a)(4), 801(a)(3); ADULTERATION
154	FLUOROCARB-154	The article appears to contain chlorofluorocarbons in violation of 21 CFR 2.125.	402(a)(2)(A), 801(a)(3); ADULTERATION
156	NO PERMIT-156	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).	1, 2, PROHIBITION WITHOUT PERMIT
157	FOREIGN OB-157	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.	501(a)(4), 801(a)(3); ADULTERATION
160	LEAK/SWELL-160	The article appears to be held in swollen containers or contains micro leaks.	402(a)(3), 801(a)(3); ADULTERATION
170	CONTAM CAN-170	The article appears to be held in a container containing a poisonous or deleterious substance which may render it injurious to health.	402(a)(1), 801(a)(3); ADULTERATION
171	CONTAINER-171	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.	402(a)(6), 801(a)(3); ADULTERATION
173	IMITATION-173	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.	403(c), 801(a)(3); MISBRANDING
175	ALCOHOL-175	The article appears to be a confectionery that bears or contains alcohol in excess of 1/2 of 1% by volume derived solely from the use of flavoring extracts.	402(d)(2), 801(a)(3); ADULTERATION
178	COL ADDED-178	The article appears to be a color additive which is unsafe within the meaning of Section 721(a).	501(a)(4), 801(a)(3); ADULTERATION
179	AGR RX-179	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.	401(d)(1), 2); IMPORTATION RESTRICTED
181	UNDER PROC-181	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.	402(a)(4), 801(a)(3); ADULTERATION
185	REDUCED-185	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a drug that a substance has been mixed or packed with so as to reduce its strength.	501(d)(1), 801(a)(3); ADULTERATION
186	INSANTY-186	The article is subject to refusal of admission pursuant to section 801(a)(3) in that 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.	501(a)(2)(A), 801(a)(3); ADULTERATION
188	FLUOROCARB-188	The article appears to be a new animal drug containing chlorofluorocarbons in violation of 21 CFR 2.125.	501(a)(5), 801(a)(3); ADULTERATION
189	FLUOROCARB-189	The article appears to contain chlorofluorocarbons in violation of 21 CFR Part 2.125.	601(a), 801(a)(3); ADULTERATION
197	COSM COLOR-197	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).	601(e), 801(a)(3); ADULTERATION
198	COLOR LBLG-198	The color additive appears to not have its packaging and labeling in conformity with such requirements as issued under section 721.	602(e), 801(a)(3); MISBRANDING
199	FEED & NAD-199	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.	501(a)(6), 801(a)(3); ADULTERATION
218	LIST INGRE-218	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the FD&C Act in that it appears to be misbranded within the meaning of Section 403(j)(2) of the FD&C Act in that it is fabricated from two or more ingredients and the label fails to bear the common or usual name of each such ingredient and/or the article purports to be	403(j)(2), 801(a)(3); MISBRANDING
223	FALSE-223	The article is subject to refusal of admission pursuant to section 801(a)(3) in that it is a device whose labeling appears to be false or misleading.	502(a), 801(a)(3); MISBRANDING
225	DEVICE GMP-225	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the methods used in and the facilities or controls used for the manufacture, packing, storage, or installation of the device do not conform to the requirements of Section 520(f)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or a condition prescribed	502(i), 801(a)(3); MISBRANDING
231	LENS CERT-231	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.	502(a), 801(a)(3); MISBRANDING
235	NOT IMPACT-235	The article appears to not have impact-resistant lenses in accordance with 21 CFR 801.410.	501(c), 801(a)(3); ADULTERATION
237	NO PMA-237	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the device appears to be a Class II device and does not appear to have in effect an approved application for premarket approval pursuant to Section 515 of the Act, or an exemption pursuant to Section 520(g)(1).	501(f)(1)(B), 801(a)(3); ADULTERATION
238	UNSAFE ADD-238	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to bear or contain an unsafe food additive within the meaning of section 409.	402(a)(2)(C)(i), 801(a)(3); ADULTERATION
241	PESTICIDE-241	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to bear or contain a pesticide chemical residue, which causes the article to be adulterated within the meaning of section 402(a)(2)(B) of the FD&C Act. Bears or contains:	402(a)(2)(B), 801(a)(3); ADULTERATION
245	EXCESS SULF-245	The article appears to contain excessive sulfites, a poisonous and deleterious substance which may render it injurious to health.	402(a)(1), 801(a)(3); ADULTERATION
249	FILTHY-249	<b>The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the article appears to consist in whole or in part of a filthy, putrid, or decomposed substance or be otherwise unfit for food.</b>	<b>402(a)(3), 801(a)(3); ADULTERATION</b>
251	POISONOUS-251	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to bear or contain a poisonous or deleterious substance which may render the article injurious to health. Contains:	402(a)(1), 801(a)(3); ADULTERATION
253	STD IDENT-253	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the FD&C Act in that it appears to be misbranded within the meaning of Section 403(g)(1) of the FD&C Act in that the article purports to be or is represented as a food for which a definition and standard of identity have been prescribed by regulations as provided by	403(g)(1), 801(a)(3); MISBRANDING
254	STD QUAT-254	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the FD&C Act in that it appears to be misbranded within the meaning of Section 403(h)(1) of the FD&C Act in that the article purports to be or is represented as a food for which a standard of quality has been prescribed by regulation as provided by Section 401 of the	403(h)(1), 801(a)(3); MISBRANDING
255	STD FILL-255	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the FD&C Act in that it appears to be misbranded within the meaning of Section 403(h)(2) of the FD&C Act in that the article purports to be or is represented as a food for which a standard or standards of fill of container have been prescribed by regulations as provided	403(h)(2), 801(a)(3); MISBRANDING
256	INCONSPICU-256	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the FD&C Act in that it appears to be misbranded within the meaning of Section 403(f) of the FD&C Act in that any word, statement, or other information required by or under the authority of the FD&C Act to appear on the label or labeling is not prominently placed	403(f), 801(a)(3); MISBRANDING
258	FLYER LBLG-258	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to contain an artificial flavoring and it fails to bear labeling stating that fact.	402(a)(3), 801(a)(3); MISBRANDING
260	FALSE-260	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the FD&C Act in that the article appears to be misbranded within the meaning of Section 403(a)(1) of the FD&C Act in that the labeling is false or misleading in any particular.	402(a)(1), 801(a)(3); MISBRANDING
262	DIETARY-262	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.	402(b), 801(a)(3); MISBRANDING
265	SUBSTITUTE-265	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears that a substance has been substituted wholly or in part for one or more of the article's ingredients.	402(b)(2), 801(a)(3); ADULTERATION
268	CONCEALED-268	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be food which has chemical damage or inferiority concealed in any manner.	402(b)(3), 801(a)(3); ADULTERATION
274	COLOR LBLG-274	The article appears to contain an artificial coloring and it fails to bear labeling stating that fact.	403(k), 801(a)(3); MISBRANDING
275	PRESRV LBL-275	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to contain a chemical preservative and it fails to bear labeling stating that fact including its function.	403(k), 801(a)(3); MISBRANDING
278	NO TAG-278	The article is subject to refusal of admission pursuant to section 536(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) in that it appears to be an electronic product to which is not affixed a certification in the form of a label or tag in conformity with section 534(h).	536(a)(b); NOT CERTIFIED
280	UNSAFE SUB-280	The article appears to bear or contain a substance which is unsafe within the meaning of Section 406.	402(a)(2)(A), 801(a)(3); ADULTERATION
281	BACTERIA-281	The article appears to contain a poisonous and deleterious substance which may render it injurious to health. Contains	402(a)(1), 801(a)(3); ADULTERATION
283	INSULIN-283	The drug appears to purport, or represented as, being composed wholly or partly of insulin and it does not appear to be from a batch with respect to which a certificate or release has been issued pursuant to section 506.REPEALED 11/97	502(k), 801(a)(3); MISBRANDING
286	POISON PKG-286	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.	502(p), 801(a)(3); MISBRANDING
288	STD LABEL-288	The article appears to not bear labeling prescribed by the performance standard established under section 514.	502(i), 801(a)(3); MISBRANDING
289	RECORDS-289	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.	502(i), 801(a)(3); MISBRANDING
290	DE IMP GMP-290	The article is subject to refusal of admission pursuant to section 801(a)(1) in that it appears that the methods used in, or the facilities or controls used for, the manufacture of the device do not conform to the applicable requirements of section 520(f).	801(a)(1); NON CONFORMING MANUFACTURING PRACTICES
292	SUBSTITUTE-292	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a drug that a substance has been substituted wholly or in part.	501(d)(2), 801(a)(3); ADULTERATION
293	SHIGELLA-293	The article appears to contain Shigella, a poisonous and deleterious substance which may render it injurious to health.	402(a)(1), 801(a)(3); ADULTERATION
295	LISTERIA-295	The article is subject to refusal of admission pursuant to Section 801(a)(3), in that the article appears to contain Listeria monocytogenes, a poisonous and deleterious substance, which may render it injurious to health.	402(a)(1), 801(a)(3); ADULTERATION
297	AFATOXIN-297	The article appears to contain aflatoxin, a poisonous and deleterious substance which may render it injurious to health.	402(a)(1), 801(a)(3); ADULTERATION
299	MBED OBJT-299	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a confectionery that has partially or completely imbedded therein any nonnutritive object.	402(d)(1), 801(a)(3); ADULTERATION
300	NONNUT SUB-300	The article appears to be confectionery and it bears or contains a nonnutritive substance.	402(d)(3), 801(a)(3); ADULTERATION
302	BUTTER-302	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 unfit for food.	402(e), 801(a)(3); ADULTERATION
304	STERILITY-304	The article appears to consist in whole or in part of any filthy, putrid, or decomposed substance.	501(a)(1), 801(a)(3); ADULTERATION
306	INSANTY-306	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 become contaminated with filth, or whereby it may have been rendered injurious to health.	402(a)(4), 801(a)(3); ADULTERATION
308	MFR INSAN-308	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the article appears to have been manufactured, processed, or packed under insanitary conditions.	801(a)(1); INSANTY MANUFACTURING, PROCESSING OR PACKING
309	FORBIDDEN-309	The article is subject to refusal of admission pursuant to Section 801(a)(2) in that it appears to be forbidden or restricted in the country in which it was produced or from which it was exported.	402(a)(5); FORBIDDEN OR RESTRICTED IN SALE
310	POISONOUS-310	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to bear or contain a poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling therefor, or, under such conditions of use as are customary or usual, except that this charge does not apply	601(a), 801(a)(3); ADULTERATION
312	FILTH-312	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to consist in whole or in part of a filthy, putrid, or decomposed substance.	601(b), 801(a)(3); ADULTERATION
313	HELD INSAN-313	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 become contaminated with filth, or whereby it may have been rendered injurious to health.	601(c), 801(a)(3); ADULTERATION
314	CONTAINER-314	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that 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.	601(d), 801(a)(3); ADULTERATION
315	ADDED BULK-315	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that 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.	402(b)(4), 801(a)(3); ADULTERATION
316	***-316	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.	402(a)(5), 801(a)(3); ADULTERATION
318	VITAMIN LBL-318	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).	403(b), 801(a)(3); MISBRANDING
319	WRONG IDEN-319	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the FD&C Act in that it appears to be misbranded as defined in section 403(b) of the FD&C Act. The article appears to be offered for sale under the name of another food.	403(b), 801(a)(3); MISBRANDING
320	LACKS FIRM-320	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the FD&C Act in that it appears to be misbranded within the meaning of Section 403(e)(1) of the FD&C Act in that the food is in package form and the label fails to bear the name and place of business of the manufacturer, packer, or distributor.	403(e)(1), 801(a)(3); MISBRANDING
321	LACKS N/C-321	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the FD&C Act in that it appears to be misbranded within the meaning of Section 403(e)(2) of the FD&C Act in that the food is in package form and the label fails to bear an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count	403(e)(2), 801(a)(3); MISBRANDING
324	NO ENGLISH-324	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the FD&C Act in that it appears to be misbranded within the meaning of Section 403(f) of the FD&C Act in that any word, statement, or other information required by or under the authority of the FD&C Act to appear on the label or labeling is not prominently placed	403(f), 801(a)(3); MISBRANDING
325	STD NAME-325	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the FD&C Act in that it appears to be misbranded within the meaning of Section 403(g)(2) of the FD&C Act in that the article purports to be or is represented as a food for which a definition and standard of identity have been prescribed by regulations as provided under	403(g)(2), 801(a)(3); MISBRANDING
327	OPTION ING-327	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.	403(g)(2), 801(a)(3); MISBRANDING
328	USUAL NAME-328	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the FD&C Act in that it appears to be misbranded within the meaning of Section 403(i)(1) of the FD&C Act in that the label fails to bear the common or usual name of the food, if any there be.	403(i)(1), 801(a)(3); MISBRANDING
329	JUICE %-329	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the FD&C Act in that it appears to be misbranded within the meaning of Section 403(j)(2) of the FD&C Act in that the food purports to be a beverage containing vegetable or fruit juice and does not bear a statement on the label in appropriate prominence on the inform	403(j)(2), 801(a)(3); MISBRANDING

330 UNSAFE COL-330	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).	501a)(4)(B), 801(a)(3), ADULTERATION
331 DR QUALITC-331	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that 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.	501(c), 801(a)(3), ADULTERATION
332 CONTAINER-332	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.	501(a)(3), 801(a)(3), ADULTERATION
333 LACKS FIRM-333	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.	502(b)(1), 801(a)(3), MISBRANDING
335 LACKS NYC-335	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.	502(b)(2), 801(a)(3), MISBRANDING
336 INCONSPICU-336	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.	502(c), 801(a)(3), MISBRANDING
337 OFF ODOR-337	The article appears to consist in whole or in part of a filthy, putrid, or decomposed substance or to be otherwise unfit for food. Contains an off odor.	402(a)(3), 801(a)(3), ADULTERATION
339 TAMPERING-339	It appears that the packing does not conform with current good manufacturing practices under 21 CFR 211.132 for tamper-resistant packaging.	501(a)(2)(B), 801(a)(3), ADULTERATION
341 REGISTERED-341	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the FD&C Act in that it appears the device is subject to listing under 510(k) and the initial distributor has not registered as required by 21 CFR 807.20 (a)(5).	502(a), 801(a)(3), MISBRANDING
342 PERSONAL-342	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a drug which requires a prescription from your doctor.	502(a)(1), 801(a)(3), MISBRANDING
343 VET LEGEND-343	The article appears to be a veterinary drug without the "Caution" statement as required by Section 503(f)(4).	502(a) & (f)(1), 801(a)(3), MISBRANDING
344 WARNINGS-344	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.	502(f)(2), 801(a)(3), MISBRANDING
346 REJECT TEA-346	The article is inferior in purity, quality, and fitness for consumption to the standards provided in section 43.TEA ACT REPEALED!	1 (2)USC41; PROHIBITED TEA
469 DISEASE-469	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.	402(a)(5), 801(a)(3), ADULTERATION
471 CSTIC LBLG-471	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.	602(a) and/or (b), and/or (c), 801(a)(3), MISBRANDING
472 NO ENGLISH-472	Required label or labeling appears to not be in English in violation of 21 C.F.R. 201.15(c)(1).	502(f)(1), 801(a)(3), MISBRANDING
473 LABELING-473	The article appears in violation of FPLA because of its placement, form and/or contents statement.	Section 4(a), 801(a)(3) Misbranding
474 COSMETLBLG-474	It appears the label does not bear the common or usual name of the cosmetic.	5(c)(3)(A), 801(a)(3) Misbranding
475 COSMETLBLG-475	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.	5(c)(3)(B), 801(a)(3) Misbranding
476 NO REGISTR-476	The article is subject to refusal of admission pursuant to section 536(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) in that it 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(f).	536(a), Failure to file initial report 501(c), 801(a)(3) Adulteration
477 HOLES-477	The quality of the article falls below that which it purports or is represented to possess, in that the devices contain defects/holes.	501(c), 801(a)(3) Adulteration
478 TISSUE-478	The article contains Saccharin, a non-nutritive sweetener, and its label or labeling fails to bear the required nutrition information.	502(a), 801(a)(3), Misbranding
479 DV QUALITY-479	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be adulterated since its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.	501(c), 801(a)(3) Adulteration
480 STAINTEEL-480	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.	502(a), 801(a)(3), Misbranding
481 LBL STEEL-481	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.	403(q), 801(a)(3), Misbranding
482 NUTRIT LBL-482	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be misbranded in that the label or labeling fails to bear the required nutrition information.	403(q), 801(a)(3), Misbranding
483 DRUG NAME-483	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.	502(e)(1), 801(a)(3), Misbranding
484 DV NAME-484	The article appears to be a device and its labeling fails to bear the proprietary or established name.	502(e)(2), 801(a)(3), Misbranding
487 SACCHARIN-487	The article contains Saccharin, a non-nutritive sweetener, and its label or labeling fails to bear the required warning statement.	502(a), 801(a)(3) Misbranding
488 HEALTH-488	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be misbranded in that the label or labeling bears an unauthorized nutrient content/health claim.	801(a)(3), 403(f)(1)(A)/(B) Misbranding
508 NO 510(K)-508	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it is a post 1976 device for which a Section 510(k) application does not appear to have been determined substantially equivalent or otherwise filed.	801(a)(3), 502(o) Misbranding
509 NONSTEL-509	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.	502(a) and/or 502(f)(1), Misbranding
2000 IMPTRHACC-2000	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).	801(a)(3), 402(a)(4) Adulteration
2020 LBLG ADVER-2020	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be misbranded because its labeling is misleading in a particular, namely that it fails to reveal facts (non-sterility) that are material with respect to consequences which may result from the use of the article according to the labeling, or advertising, or use.	402(a)(1), 801(a)(3), MISBRANDING
2040 SUTLETLB-2040	The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be misbranded because it appears to contain sulfites, a fact material to sulfite-sensitive individuals who must avoid the ingredient due to potential health consequences from its consumption, and 403(a)(1).	403(a)(1), 801(a)(3), MISBRANDING
2060 AGRINSULIN-2060	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	801(d)(1)(2), IMPORTATION RESTRICTED
2080 COUMARIN-2080	The article appears to bear or contain Coumarin, a poisonous or deleterious substance, which may render it injurious to health.	402(a)(1), 801(a)(3), Adulteration
2100 POISONOUS-2100	Istheria (test* ddd	402(f)(1)(B), 801(a)(3) Adulteration
2120 UNSFIDTSP-2120	The article is subject to refusal of admission pursuant to section 801(a)(3) of the FD&C Act in that it 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.	402(f)(1)(B), 801(a)(3) Adulteration
2160 LACK NOTIF-2160	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(f).	301(a)
2200 DIET INGRE-2200	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.	402(a)(3), 801(a)(3), Adulteration
2201 BSE FLTR-2201	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be unfit for food.	402(a)(3), 801(a)(3), Adulteration
2202 INSAN BSE-2202	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.	402(a)(4), 801(a)(3), Adulteration
2220 INGREDF IL-2220	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.	402(a)(4), 801(a)(3), Adulteration
2240 COSMETIC-2240	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that 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.	601(c), 801(a)(3), Adulteration
2280 DIRSEXMP-2280	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) and it lacks adequate directions for use.	502(f)(1), 801(a)(3), MISBRANDING
2300 DIETARYLBL-2300	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the FD&C Act in that it is a dietary supplement that appears to be misbranded within the meaning of Section 403(c)(2)(B) of the FD&C Act in that the label or labeling fails to identify the product by using the term "dietary supplement", which term may be modified with "dietary supplement" or "dietary supplement and/or food additive".	403(c)(2)(B), 801(a)(3), MISBRAND
2341 DIOMN-2341	The article appears to bear or contain diosmin and/or PCB compounds, poisonous or deleterious substances and/or unapproved food additives which may render it injurious to health.	402(a)(1), 402(a)(2)(A), 402(a)(2)(C)(i), 801(a)(3)-Adulterated
2360 HISTAMINE-2360	The article appears to bear or contain histamine, a poisonous and deleterious substance in such quantity as ordinarily renders it injurious to health.	402(a)(1), 801(a)(3), Adulteration
2380 NO PMA/PPD-2380	The article appears to be a class III dew/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).	501(f)(1)(A), 801(a)(3), ADULTERATION
2400 COLOR-2400	Article appears to contain the radionuclide, Cesium-137, a poisonous and deleterious substance which may render it injurious to health.	402(a)(1), 801(a)(3), Adulteration
2420 RADIONUC-2420	The article appears to contain 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.	402(f)(1)(A), 801(a)(3) Adulteration
2460 UNSFIDTUS-2460	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a dietary supplement that contains, or a dietary ingredient that is, a dietary ingredient that renders it adulterated under section 402(a)(1) under the conditions of use recommended or suggested in the labeling of such dietary supplement.	402(f)(1)(D), 801(a)(3) Adulteration
2480 XPRFINSOL-2480	The article appears to be a device which requires a prescription from your doctor.	502(a), 502(f)(1), 801(a)(3), MISBRANDING
2580 MFRHACP-2580	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the Act in that it appears to have been prepared, packed or held under insanitary conditions whereby it may have been rendered injurious to health in that it appears to have been processed in violation of 21 CFR 123.6(a) and 123.8(a).	402(a)(4), 801(a)(3)
2640 CYCLAMATE-2640	The article appears to bear or contain cyclamate, an unsafe food additive within the meaning of Section 409	402(a)(2)(C), 801(a)(3)
2680 SACCHARLB-2680	The article contains Saccharin, a non-nutritive sweetener, and its label or labeling fails to list it as an added ingredient	403(i), 803(a)(3) Misbranding
2720 DUJCN-2720	The article appears to bear or contain dulcin, an unsafe food additive within the meaning of Section 409	402(a)(2)(C), 801(a)(3)
2740 DR QUALITY-2740	The article is subject to refusal of admission pursuant to Section 801(a)(1) in that the methods used in, or the facilities or controls used for, the manufacture, packing, storage, or installation of the device do not conform to the requirements of Section 520(f)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) or a condition prescribed	501(h), 801(a)(1), ADULTERATION
2780 DEVCEGMP-2780	The article appears to consist in whole or in part of any filthy, putrid, or decomposed substance, namely, potentially infectious organisms	501(a)(1), 801(a)(3), ADULTERATION
2800 POSS N/STR-2800	The article is subject to refusal in that it is calibrated in units not commonly used in the United States	502(f)(1), 801(a)(3), misbranding
2820 CALIBRATED-2820	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.	501(a)(2)(A), 801(a)(1), Adulteration
2840 BSE DRUGS-2840	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to contain a new animal drug (or conversion product thereof) that is unsafe within the meaning of Section 512. Product contains	402(a)(2)(C)(ii), 801(a)(3), ADULTERATION
2860 VETDRUGRES-2860	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to contain a new animal drug (or conversion product thereof) that is unsafe within the meaning of Section 512. Product contains	503(b)(A) & 502(c), 801(a)(3), MISBRANDING
2880 KOCOMPOUND-2880	The article appears to contain a food additive, namely chloramphenicol, that is unsafe within the meaning of 21 U.S.C. 348.	402(a)(2)(C)(i), 801(a)(3), ADULTERATION
2900 CHLORAMP-2900	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:	402(a)(2)(B), 802(a)(B), ADULTERATION
2920 PESTICIDES-2920	The cosmetic's labeling appears to be false or misleading within the meaning of Section 201(n).	602(a) & 801(a)(3), MISBRANDING
2940 COSM MISB-2940	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.	403(i), 801(a)(3)
2960 FALSECAT-2960		
2980 BIO TOKIN-2980	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	402(a)(1), 801(a)(3), Adulteration
2981 BIO TOKIN-2981	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.	502(e)(1), 801(a)(3), Misbranding
3000 N-RX INACT-3000	The article appears to bear or contain a food additive, Japanese star anise, that is unsafe within the meaning of section 409.	402(a)(2)(C)(i), 801(a)(3), Adulteration
3020 STARANISE-3020	The article is subject to refusal of admission to pursuant Section 801(a)(3) in that it appears to contain Hepatitis A Virus, a poisonous or deleterious substance which may render it injurious to health.	Section 801(a)(3), 402(a)(1), ADULTERATION
3040 HEPATITIS-A-3040	The article appears to contain a poisonous or deleterious substance, namely chloramphenicol, which may render it injurious to health.	402(a)(1), 801(a)(3), ADULTERATION
3060 POIS CHLOR-3060		501(i), 801(a)(3)
3080 DEVNOEXPT-3080	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that it appears to be a device for investigation use for which no exemption has been granted as prescribed by Section 520(g)	501(i), 801(a)(3), ADULTERATION
3081 INVDEVCE-3081	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.	402(f)(3)(B), 801(a)(3), ADULTERATION
3100 ANDRO-3100	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 it is adulterated under section 402(a)(1).	801(a)(3), 402(f)(1)(A), ADULTERATION
3120 EPHEADK-3120	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.	801(a)(3), 403(u) Misbranding
3140 SBGNSENG-3140	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the product 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 fo	402(a)(4), 801(a)(3), ADULTERATION
3160 NONSP-VER-3160	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.	402(a)(4), 801(a)(3), ADULTERATION
3161 NONSP-PRC-3161	The article is subject to refusal of admission pursuant to Section 801(a)(3) of the Act, in that it appears to contain Patulin, a poisonous and deleterious substance which may render it injurious to health.	402(a)(1), 801(a)(3), ADULTERATION
3180 PATULIN-3180	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:	602(a) & (f)(1), 801(a)(3), MISBRANDING
3200 CSMA MIBS-3200	The article is subject to refusal of admission, pursuant to Section 801(a)(3) in that it appears to bear or contain a food additive, namely, nitrofurans, that is unsafe within the meaning of section 409.	402(a)(2)(C)(i), 801(a)(3), Adulteration
3220 NITROFURAN-3220	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).	402(a)(4), 801(a)(3), ADULTERATION
3240 NOCONTODE-3240	Required label or labeling appears to not be in English in violation of 21 C.F.R. 801.15(c)(1)	502(c), 801(a)(3), MISBRANDING
3260 NO ENGLISH-3260	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&C Act. Based on information available to FDA, it appears that it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under Section 510 of t	502(o), 801(a)(3), MISBRANDING
3280 FRNMFREG-3280	The label fails to declare all major food allergens present in the product, as required by section 403(w)(1).	403(w), 801(a)(3), Misbranding
3300 ALLEGRIN-3300	The product is misbranded under Section 403(b) 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)].	403(b), 801(a)(3), MISBRANDING
3320 TRANSFR-3320	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.	801(d)(1)(2), IMPORTATION RESTRICTED
3340 DE/EX KIT-3340	The article is subject to refusal of admission pursuant to Section 801(a)(3) in that the infant formula appears to be adulterated in that it does not provide the nutrients required by 21 CFR 107.100	412(a)(1), 801(a)(3), Adulterated
3361 NUTR DEF-3361	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.	403(f), 801(a)(3), MISBRAND
3380 EXPRED-3380	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.	501(c), 801(a)(3) Adulteration
3400 PB-FOOD-3400	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.	402(a)(1), 801(a)(3), Adulteration
3420 MELAMINE-3420	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.	402(a)(1), 801(a)(3), Adulteration
3421 MELAMINE-3421	The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to bear or contain a food additive, namely melamine and/or a melamine analog, that is unsafe within the meaning of section 409.	402(a)(2)(C)(i), 801(a)(3), ADULTERATION
3422 UNFIT4FOOD-3422	The article is subject to refusal of admission pursuant to section 801(a)(3) in that it appears to be unfit for food.	402(a)(3), 801(a)(3), ADULTERATION
3440 MELAMINE-3440	The article is subject to refusal of admission in that it appears to bear or contain a food additive, namely melamine and/or a melamine analog, that is unsafe within the meaning of section 409.	402(a)(2)(C)(i), 801(a)(3), ADULTERATION

