**Exhibit 5-3**
**MODEL CHARGES**

SPECIMEN CHARGE

(Do not quote the section of the Act listed below on the Charge Sheet)

**Adulterated Foods**

402(a)(1)

- The soybeans contain an added poisonous or deleterious substance, namely, crotalaria seeds, which may render them injurious to health.
- The frozen eggs contain added salmonella microorganisms, pathogenic bacteria, which may render them injurious to health.
- The article contains selenium, a poisonous or deleterious substance, in a quantity that would ordinarily render it injurious to health.

402(a)(2)(A)

- The articles contains an added deleterious substance, namely, metal fragments, which is unsafe since it is not required in the production of this food and can be avoided by good manufacturing practices.
- The cod fillets contain oxytetracycline that is unsafe, since oxytetracycline is not required in the production of this food and can be avoided by good manufacturing practices.

NOTE: Generally, the use of Section 402(a)(2)(A) as a basis for charges should be limited; other sections, such as 402(a)(1), are usually preferred.

402(a)(2)(B)

- The berries contain heptachlor, which is not generally recognized as safe, and for use of which a tolerance has not been prescribed by regulation.
- The cabbage contains excessive Toxaphene.

402(a)(2)(C)

- The article contains a food additive, namely lead, which is unsafe within the meaning of Section 409(a) since its use and intended use are not in conformity with a regulation or exemption in effect.

402(a)(2)(D)

- The meat intended for human food contains a new animal drug, namely MGA, which is unsafe in that there is no approved new animal drug application in effect for this use.

402(a)(3)

- The article contains insect parts and insect excreta.
- The article contains rodent excreta pellets.
- The nuts are rancid.

- Some of the cans contain decomposed salmon.
- The catsup contains decomposed tomatoes.
- The peanut butter contains grit.

402(a)(4)

- The factory (warehouse) in which it was prepared and packed (held) was infested with rodents and insects, which may have contaminated it.

402(a)(5)

- Some of the boxes contain emaciated and diseased birds.
- Some of the boxes contained birds that were not slaughtered but that died from other causes.

402(a)(7)

- The article has been subjected to radiation, not provided for by the Food Additives Regulations.

402(b)(1)

- The article is deficient in Vitamin B.
- The butter contains less than 80% milkfat.

402(b)(2)

- Mineral oil has been used to replace part of the vegetable oil.
- Chicory has been used in part instead of coffee.

402(b)(3)

- Blemished, old potatoes have been colored and waxed to resemble new potatoes and to conceal the blemishes.

402(b)(4)

- The ground pepper contains ground olive seeds.
- The poppy seeds are brown and have been artificially colored to appear to be blue poppy seeds.

402(c)

- The article contains a color additive, namely, "butter yellow," not permitted by regulation for use in food.
- The article contains a color additive, namely, FD&C Purple Number 8, for which no tolerance has been established.

402(d)

- Some pieces of the candy contain a metallic toy.
- The candy is filled with alcohol.

402(e)

- The article contains vegetable oil that is rancid.
- The milk used to manufacture the butter contained flies and manure.

**Misbranded Foods**

403(a)

- The label falsely represents it to contain a significant amount of honey but the amount present, if any, is inconsequential.
- The label bears statements that falsely represent, in the setting in which they are presented, that the article will supply an unusually large amount of protein in a quantity which is low in calories, and that the article is therefore of significant value for weight reducing.
- The labeling falsely represents that the product contains copper, folic acid, cobalt and calcium pantothenate.
- The label falsely represents the article to be canned peas, whereas the article is canned spinach.

403(b)

- It was offered as lemon extract by the price list sent to the consignee on or about May 2, XXXX, but it is in fact an extract of lemon grass oil.

403(c)

- The word "Imitation" on the label is in type of smaller size and less prominence than the type in which the words "Vanilla Extract" appear.
- The label fails to bear the name "Imitation Strawberry Preserves."

403(d)

- The can has a depressed top and bottom and contains a thick corrugated inner liner, which give the container the appearance of containing more nuts than it does.
- The container is slack-filled.

403(e)(1)

- The label fails to bear the name of the manufacturer, packer, or distributor.

403(e)(2)

- The label statement "net weight 4 oz." is inaccurate.
- The article is short weight.

403(f)

- The statement of ingredients on the label is inconspicuous.
- The name and address of the manufacturer is printed on the

cellophane bag in white ink and lacks contrast with the white candy mints contained therein.

403(g)(1)

- The article is represented as raspberry preserves but contains less fruit than the standard of identity requires.
- The article purports to be French dressing but contains less fat than specified in that standard.
- The egg noodles are deficient in egg solids content.

403(g)(2)

- The article is bleached flour but the label does not state that it is bleached.
- The article purports to be enriched macaroni, and its label fails to bear the name of that food.
- The article purports to be Fruit Butter, but its label fails to bear the name of the optional ingredient, lime juice, present in the food.

403(h)(1)

- The article contains excessive blemished fruit but its label does not bear the statement of substandard quality prescribed for canned peaches.
- Its quality falls below the standard for canned tomatoes, since it contains excessive peel.

403(h)(2)

- The cans are underfilled but the label does not bear the statement of substandard fill prescribed for canned peas.

403(i)(1)

- The article is ground cinnamon but its label does not bear the name "ground cinnamon."

403(i)(2)

- Flour is present but is not named in the label listing of ingredients.
- The label fails to bear a statement of ingredients of the article by their common or usual names.

403(j)

- Its label fails to bear a statement of the percentage of the USRDA for the vitamins B(1), B(2), niacinamide and the mineral iron, as required by the special dietary regulations.
- The label fails to state the percent by weight of methylcellulose present; and in juxtaposition with name of such constituent, the word "non-nutritive," as required by the special dietary regulations.

403(k)

- The labeling fails to state the fact that a chemical preservative has been added.
- The article is artificially colored, but its labeling fails to state that fact.

403(l)

- The oranges contain biphenyl (diphenyl applied post harvest), but its shipping container fails to bear labeling declaring the name and function of the pesticide chemical.

403(m)

- The article is a color mixture but its label does not declare the name of the color components contained therein.

**Adulterated Drugs**

501(a)(1)

- The aspirin tablets contain rodent hairs.

501(a)(2)(A)

- The plant in which the aspirin tablets were manufactured was infested with rodents which may have contaminated them.

501(a)(2)(B)

- The door of the sterile filling room was left open while filling bottles of an eye solution.
- The methods used in its packing do not conform to current good manufacturing practices in that Isopropyl alcohol is labeled as Citrate of Magnesia.

501(a)(3)

- Its container is composed in part of lead, which may render the contents injurious to health.

501(a)(4)(A)

- The color used is in excess of the limits prescribed in the regulations.

501(a)(4)(B)

- FD&C Red #4 intended for use in a drug for internal administration, and such use is for coloring purposes only.

501(a)(5)

- The article is a new animal drug and there is no approved new animal drug application in effect for this drug.

501(a)(6)

- The cattle feed contains a new animal drug, namely Carbadox, which is unsafe in that there is no approved new animal drug application in effect for this use.

501(b)

- The article purports to be an official NF drug but fails to comply with the compendium's standard for strength.
- It contains cresol, a substance not permitted by the U. S. Pharmacopeial Monograph for Water for Injection, which the drug purports to be.
- Magnesium carbonate, which the NF formula requires in Solution of Magnesium Citrate, has been replaced by sodium carbonate.

501(c)

- The article contains Neomycin Sulfate which is below the potency declared on the label.
- The quality of the article namely, Rubber Prophylactics, falls below that which it is purported to possess.

501(d)(1)

- The article has been mixed or packed so as to reduce its quality or strength.

501(d)(2)

- P-aminosalicylic acid has been substituted in part for conjugated para-amino salicylic ascorbate.

**Misbranded Drugs**

502(a)

- Its labeling represents it as a treatment for influenza and related diseases, but it is not an effective treatment for these diseases.
- The article falsely claims that it will remove ascarids from hogs.

502(b)(1)

- Its label does not bear the name and place of business of the manufacturer.

502(b)(2)

- Its label does not bear an accurate statement of the quantity of contents.

502(c)

- The statement "24 tablets" appears on the back label and is on a pink label in red type.

502(e)(1)(A)(i)

- The label does not show that the drug is aspirin.

502(e)(1)(A)(ii)

- The quantity of bromide per tablet is not stated on the label.
- Its label fails to list all of the active ingredients.

502(f)(1)

- The directions do not state the uses of the drug.
- Its (O-T-C drug) labeling does not contain directions adequate for the treatment of diabetes, for which use the drug is recommended in advertising (as distinguished from labeling).
- The prescription drug lacks adequate full disclosure information.

502(f)(2)

- The labeling does not warn against use of the drug in case of nausea, vomiting, abdominal pain, or other symptoms of appendicitis.
- The labeling gives no warning that use of the drug in excess of what the directions call for may result in nervousness and sleeplessness.

502(g)

- It is not packaged in tight containers as required by the United States Pharmacopoeia.

502(i)(1)

- The container is slack-filled.

502(i)(2)

- It is an imitation of citrate of magnesia.

502(i)(3)

- The article, namely argel leaves, is offered for sale as senna.

502(j)

- It is dangerous to health when one tablet is taken every three hours as recommended in the labeling.
- It is dangerous to health when taken in the dosage suggested in its labeling.

502(m)

- The label fails to provide directions for use to preclude adding excessive color additive to the drug.

502(n)(1)

- The advertisement for Miltown which appeared in the May 19, 20XX edition of the Pleasant Medical Journal did not show the established name.

502(n)(2)

- The advertisement for "Triple Sulfa" tablets which appeared ____ etc. ____ did not list the active ingredients by their established names.

502(n)(3)

- The advertisement for "Triple Sulfa" tablets which appeared in the May 19, 20XX edition of _____ contained or recommended indications for use or a dosage recommendation, but not the brief summary of side effects, contraindications, and effectiveness.

502(o)

- The potassium chloride tablets were manufactured in an unregistered plant.

503(b)(4)(A)

- The label for the article, namely chloralhydrate, does not bear the symbol “Rx only”.

503(b)(4)(B)

- The aspirin tablet label bears the symbol “Rx only,” but the drug is not entitled to such designation.

505(a)

- The article, namely, Meprobamate, is a new drug and was shipped in interstate commerce without an approved new drug application.

**Cosmetics**

601(a)

- The article contains paraphenylenediamine, a coal tar dye which is a deleterious substance, but its label does not carry adequate warnings or directions to make a preliminary patch test before use.
- It contains formaldehyde, a deleterious substance.

601(b)

- Some of its components contain rodent excreta pellets.

601(c)

- The plant in which the article was prepared was infested with rodents.

601(d)

- Its container is composed in part of lead.

601(e)

- The color used is not authorized by the regulations (or is in excess of the limits prescribed in the regulations.)

602(a)

- The article is represented as containing a substantial amount of lanolin, but lanolin is a minor constituent of the cream.

602(b)(1)

- The label for the eye shadow does not bear the name and location of the manufacturer, namely, New York Pencil Co., Inc., New York, N.Y.

602(b)(2)

- The article does not bear a statement of the quantity of contents.

602(c)

- The statement of the quantity of contents appears on the bottom of the container (oval jar).

602(d)

- The nontransparent container is composed of an outer and inner wall with a 1/8 inch space between the walls.

602(e)

- The label fails to provide directions for use to preclude adding excessive color additive to the cosmetic.

**Title 42**

351(a)

- The Source Plasma (Human) was drawn and shipped from an unlicensed establishment.

- The label fails to bear the expiration date and license number of the establishment.

351(b)

- The label states the blood is Hgb negative, but the records show the unit is Hgb positive.
- The donor number on the unit label is false.

- The product is pooled serum, but the label falsely states it was drawn from one donor.

351(c)

- Inspection of the establishment by a duly authorized investigator was refused.

351(e)

- Officers of your firm interfered with the investigator in the performance of his duties by refusing to provide necessary records for his review.

**Title 18, Section 1001**

- The firm was aware that test animals had died, but concealed that fact.
- You advised FDA Investigators that you had no connection with the study, knowing the statement to be false.
- The study that was submitted with NDA 80-125 contains fictitious entries.
- The documents submitted in support of your application contain false statements.