APPENDIX TO LEGAL ANALYSIS

Examples of FDA's Regulation of Products as Drugs or Devices Based on the Product's Inherent Nature, Actual Use, or Its Effect on the Structure or Function of the Body

FDA has, on a number of occasions, asserted jurisdiction over a product even though the product's labeling and the vendor's advertising or other express representations did not establish that the product was a drug or a device within the meaning of the Act. The agency has found "intended use" and "intended effects" based on the inherent nature of the product, its actual use or effects, or a combination of these factors. Some examples follow:

1. Stimulant Narcotic Chewed or Used as Tea: Beginning in the early 1980's, FDA regulated as unapproved drugs imports of catha edulis, or "khat," a shrub whose leaves act as a stimulant narcotic that affects the central nervous system when chewed or used as tea, even though the agency did not have any information about or claims by vendors. FDA Import Alert 66-23 (March 26, 1982, revised April 2, 1986, and February 9, 1993). FDA issued an import alert for the product, deeming it a drug in the absence of any labeling or other material that would establish intended use. See FDA Import Alert 66-23 (March 26, 1982). FDA initiated a seizure of "khat" in Buffalo in 1985 and the product was ultimately forfeited and destroyed. FDA Import Alert 66-23 (April 2, 1986 revision). Knowledge of khat's use came from United Nations reports and other general sources of information about customs and practices regarding the use of khat. Id.

2. Imitation Cocaine: FDA took numerous enforcement actions in the 1980's against "caine" products that were used to imitate cocaine. "Caine" contained bulk anesthetic powders, such as lidocaine or mannitol, and was often sold as "incense" or "novelty cocaine."

Memorandum from Chief, Prescription Drug Compliance Branch (August 4, 1982), reprinted in Rx Drug Study Bulletin #258. The agency used laboratory analyses of the products, the manner in which the products were offered and sold, such as through magazines not associated with the legitimate drug industry (e.g. the National Enquirer, High Times, Soldier of Fortune, and Easy Rider) and at headshops with other drug paraphernalia, and "street" information that the products provide a "cheap high" to determine the products' intended use. See id. In 1984, the government seized a "caine" product from Golden Rod Music in Dayton, OH. FDC 64350, Case No. C-3-84-686 (S.D. Ohio). The product consisted of more than 25 percent ephedrine, as determined by laboratory analysis. Id. Also in 1984, FDA issued a regulatory letter to Mid-America Drug Co., Evansville, IN., concerning marketing of "caine" products. FDA Administrative File for Mid-America Drug Co., regulatory letter 84-DT-12. The firm voluntarily discontinued sales of the products, as did several other firms that received regulatory letters at about the same time. Id., response to regulatory letter 84-DT-12; see also, FDA Administrative File for Sam's Imports, Dearborn, MI, regulatory letter 85-DT-3 and response; FDA Administrative File for NALPAC, Ltd., Oakpark, MI, regulatory letter 85-DT-5 and response; FDA Administrative File for Tower Enterprises, Ida, MI, regulatory letter 85-DT-2 and response. In 1994, the government prosecuted Edwin and Thomas Dews in Michigan for selling a product called "Milky Trails," labeled as a room odorizer but in fact containing lidocaine. Case No. 94 CR 20040-BC (E.D. Mich.).

3. Hormones in Topical Preparations: The agency has formally taken the position that any statement in the labeling indicating that "hormones" are present in topical products will be considered to be an implied claim for therapeutic purposes, or to affect the structure or

function of the body, and will make the product a drug, even in the absence of more specific claims. 58 Fed. Reg. 47611, 47612 (September 9, 1993); Drug Study Bulletin No. 67 (March 28, 1994); see also 54 Fed. Reg. 40618, 40619 (October 2, 1989). The agency has also taken the position that even in the absence of labeling indicating that "hormones" are present in the product, the mere presence of hormones at levels that affect the structure or any function of the body, or the inclusion of certain hormones that do not have any legitimate cosmetic uses, would be sufficient for a determination that the product is a drug. 58 Fed. Reg. at 47611.

4. Fluoride in Dentifrice Products: FDA considers dentifrice products containing fluoride to be drugs, irrespective of whether any claims are made, because fluoride is widely accepted as an anti-cavity agent by the dental products industry and consumers, and because fluoride affects the structure of the tooth. See 59 Fed. Reg. 6084, 6088 (February 9, 1994); see also 50 Fed. Reg. 39854 (September 30, 1985).

5. Thyroid in Food Supplements: In 1984, the government seized and destroyed a thyroid-containing product that had been marketed as a food supplement by an Arkansas firm. FDC 64270, Case No. B-C-84-61 (E.D. Ark.). FDA had concluded that the product was a drug, based on the recognized effects of thyroid products on the structure and function of the human body.

6. Interferon: In 1983, FDA established a due diligence requirement regarding manufacturers' distribution of interferon, a biologic product composed of proteins. See 48 Fed. Reg. 52644 (November 21, 1983). At the time, interferon could be used only for investigational purposes in laboratory animals and tests in vitro. However, interferon received wide media coverage as a potential "miracle cure" in the treatment of cancer and viral infections in humans.

Because of its concern over diversion of interferon to unapproved uses, the Agency issued the notice to prevent use of interferon in humans.

7. Eye Ailment Device: In the 1960's, FDA undertook an enforcement action against a metal tube containing a light bulb, round metal discs, and colored glass filters used by a medical practitioner in his office in the treatment of various eye malfunctions and conditions. A district court upheld the Agency's conclusion that this use made the tube a device, even though the practitioner made no claims for the product. United States v. An Article of Device . . . Labeled in Part: "Cameron Spitler Amblo-Syntonizer", 261 F. Supp. 243, 245 (D. Neb. 1966).

8. Novelty Condoms: In early 1994, FDA took the position that "novelty condoms" that are usable as condoms would be regulated as condoms even in the absence of express claims (e.g., for birth control or to prevent sexually transmitted diseases). Letter from Ronald Johnson, Director, Office of Compliance, CDRH, to Manufacturers, Distributors, and Importers of Condoms, February 23, 1994. The agency's position was based on the belief that, because of the inherent nature and exclusive use of the article, people would actually use the condoms for prophylactic purposes even though they were not so labeled. The Agency stated that "[l]abeling a functional condom as a novelty is not sufficient" to escape the regulatory requirements applicable to condoms specifically and medical devices in general. Instead, a manufacturer would have to render the product completely unusable as a condom. Id.

9. Noncorrective Tinted Contact Lenses: The agency has taken the position that tinted contact lenses that do not correct or improve vision and are promoted to enhance eye color are medical devices. This position is based on the fact that all contact lenses, including neutral lenses, have a physiological effect on the eye. In 1986, the government obtained a consent

decree of permanent injunction against the sale of a system used to make noncorrective tinted contact lenses on the ground that the system causes adulteration of a medical device, the lenses. FDA INJ 1145, United States v. International Hydron Corp., No. 87-2129 (E.D.N.Y.).

10. Sunscreens: Between 1940 and the 1970's, FDA changed its position regarding the degree to which sunscreens were drugs under the Act. See 58 Fed. Reg. 28194 (May 12, 1993). FDA had stated in a 1940 advisory opinion that a product promoted for the prevention of damage from the sun was a drug while a product promoted for acquiring an even tan was a cosmetic. Id. at 28204. FDA changed its view of the latter category of products, however, because "[s]ince 1940 . . . there has been a significant body of information developed on the harmful effects of the sun on human health and a significant change has occurred in consumer perception of the purpose of suntanning products." Id. FDA explained that sunscreen products affect the structure and function of the body by "altering the normal physiological response to solar radiation," and that consumers expect protection from such products irrespective of the way in which such products are promoted. Id.

11. Tanning Booths: FDA has taken the position that tanning booths are devices under the Act because, by exposing the body to ultraviolet rays, they are intended to affect the structure or function of the body. Based on this position, the Agency has initiated seizure actions in recent years against various tanning booths, including, among others, those in the possession of Chic Wig Boutiques, Clarksville, Indiana. FDC 66099, Case No. NA 91-64-C (N.D. Ind.). The Indiana firm signed a consent decree with regard to this device. Id.; see also FDC 66224 (Chic Tanning Studio, Tampa, Florida), Case No. 92-CV-70829-DT (M.D. Fl.); FDC 65453 (Sunburst Sun Spa, Anchorage, Alaska), Case No. A-87-625-CIV (D. Alaska).