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**Compliance Policy Guide
Section 101.100 FDA Considerations for Recommending Charges
Under 21 U.S.C. §331(a) or (d) for Causing the Introduction of
Violative Products into Interstate Commerce
Guidance for FDA Staff**

Submit one set of either electronic or written comments on this guidance at any time. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number of this Compliance Policy Guide: FDA-2016-D-3329.

For questions regarding this document contact Anthony Taube with the Office of Regulatory Affairs (ORA) at 240-402-4565.

**U.S. Department of Health and Human Services
Food and Drug Administration
Office of Regulatory Affairs**

October 2016

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this guidance.

I. Introduction:

The purpose of this Compliance Policy Guide is to provide guidance to FDA staff when considering recommending charges under 21 U.S.C. §331(a) or (d), the Food Drug & Cosmetic Act §301(a) or (d).

FDA's guidance documents, including this guidance document, do not establish legally enforceable responsibilities. Instead, guidances describe the agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

Sections 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. §§ 331(a) and (d)) prohibit introducing, delivering for introduction, or causing the introduction or delivery for introduction into interstate commerce of certain products that violate the FD&C Act, such as adulterated or misbranded food, drugs, devices, tobacco products and cosmetics, as well as unapproved new drugs.

Over the past few decades, an increasingly global and national marketplace has expanded the number of complex multi-party transactions involving FDA-regulated products. Modern technologies such as the Internet have made direct sales from global and national manufacturers and distributors to a wider range of middlemen both more feasible and more common. Given the changes in technology and the greater variety of transactions, FDA is clarifying its enforcement policy with respect to certain types of conduct under section 301(a) or (d) of the FD&C Act, under a causing theory.

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As the Supreme Court has held, the overriding purpose of the FD&C Act is to protect the public from unsafe and ineffective products by regulating those products throughout the distribution chain. To ensure the integrity of that distribution chain, in considering judicial actions involving potential charges under section 301(a) or (d) of the FD&C Act for causing the introduction of violative products into interstate commerce through purchasing or ordering such products (“purchasing conduct”), FDA staff recommending enforcement actions to the United States Department of Justice (DOJ) will focus on only purchasing conduct by those firms or individuals who perform a direct or facilitating role in distributing FDA-regulated products, rather than on ultimate consumers, as discussed below.

III. Policy

FDA staff must carefully consider any decision to recommend a civil injunction or criminal prosecution involving purchasing conduct that violates section 301(a) or (d) of the FD&C Act based on a “causing” theory.

A. Factors FDA Staff will Consider

FDA staff will apply the following criteria in evaluating such potential charges:

1. FDA staff will **not** recommend to DOJ a criminal prosecution charging an ultimate consumer with a violation of section 301(a) or (d) for purchasing conduct. In determining whether an individual is an “ultimate consumer,” agency staff may look behind any representation by the individual that the products at issue are for personal use. In doing so, staff will take into account factors such as the volume of product ordered and shipped to the individual, the frequency of such orders and shipments, and any other indicia of distribution beyond personal use.
2. Generally, FDA staff also will **not** recommend to DOJ a civil injunction against an ultimate consumer (as defined above) premised on a violation of section 301(a) or (d) for purchasing conduct. However, an exception to this general policy may be made where both FDA’s Deputy Commissioner for Global Regulatory Operations and Policy and Chief Counsel: (1) specifically find that a compelling public health need or other compelling circumstances warrant bringing such an action, AND (2) authorize the agency to recommend such an action to DOJ. Those officials will not delegate such authority.
3. When there is sufficient evidence supporting either (A) a charge under section 301(c) for receiving violative products in interstate commerce and proffering their further delivery or (B) a subsequent violation of section 301(a) or (d) after receipt of the violative products, FDA staff will **not** recommend to DOJ a civil injunction or a criminal prosecution against a middleman based on purchasing conduct.
4. When there is not sufficient evidence under paragraph 3(A) or 3(B), above, FDA staff will **not** recommend to DOJ a civil injunction or criminal prosecution against

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a middleman based on purchasing conduct in violation of section 301(a) or (d) except under the following circumstances:

- A. The purchasing conduct involves facilitating distribution between third parties and either other middlemen or ultimate consumers; **OR**
 - B. Both FDA's Deputy Commissioner for Global Regulatory Operations and Policy and Chief Counsel: (1) specifically find that a compelling public health need or other compelling circumstances warrant bringing such a charge AND (2) authorize the agency to recommend such a charge to DOJ. Those officials will not delegate such authority.
5. If, after following the process described in paragraphs 2 and 4(B) above, FDA's Deputy Commissioner for Global Regulatory Operations and Policy and Chief Counsel authorize the agency to recommend charges to DOJ, FDA staff will advise DOJ's Consumer Protection Branch of the recommendation.

These criteria are intended solely for use by FDA personnel, do not create or confer any rights or benefits for or on any person, and do not operate to bind FDA.

B. Collaboration with Federal Law Enforcement Agencies

The importation or distribution of misbranded or adulterated articles remains unlawful under the FD&C Act. *See* 21 U.S.C. §§ 331, 355, 381. FDA staff should, as appropriate, confer with other federal law enforcement agencies, including DOJ and the U.S. Department of Homeland Security/Customs and Border Protection, to prevent or deter the unlawful importation or distribution of misbranded or adulterated articles. *See, e.g.*, 18 U.S.C. §§ 541, 542, 545; 19 U.S.C. §§ 1592, 1595a; 21 U.S.C. §§ 331-334, 381.

IV. Regulatory Action Guidance

Refer to the [FDA Regulatory Procedures Manual](#) section Chapter 6 for information on Judicial Actions.

Issued: 10/18/2016