



**JUSTICE MANUAL**



**Title 4: Civil**

**4-8.000 - Consumer Protection**



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## 4-8.010 - Introduction

The Consumer Protection Branch (“CPB”) handles criminal and civil litigation and related matters arising under federal statutes that protect consumers’ health, safety, economic security, and identity integrity. The Branch is responsible for criminal and civil actions under statutes administered by the Food and Drug Administration, the Federal Trade Commission, and the Consumer Product Safety Commission, and under certain statutes administered by the National Highway Traffic Safety Administration. See 28 C.F.R. § 0.45(j); [JM 4-1.313](#). The Branch also defends against challenges to government programs and policies in consumer-related areas, including actions of the Food and Drug Administration and the Consumer Product Safety Commission.

CPB, created in 1971, has been central in developing the caselaw under the various consumer protection statutes over which it has jurisdiction, and the Branch has considerable expertise in these areas of the law.

CPB frequently partners with U.S. Attorney's Offices ("USAOs") and other Department components to advance complex investigations and litigation. Through such collaboration, CPB is able to share substantial resources related to investigative leads, evidence review, and model pleadings. Among other things, CPB’s coordination with USAOs and others ensures that unique legal, policy, and factual concerns, as well as necessary approvals, are appropriately considered in litigation under CPB’s statutes.

[updated January 2021]

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## 4-8.100 - Persons to Contact at CPB

Contact information for CPB can be found in the directory “Expertise in the Civil Division.”

[updated April 2018]

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# 4-8.200 - Federal Food, Drug, and Cosmetic Act Litigation

To ensure uniform and balanced application of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301, *et seq.*, the Consumer Protection Branch (CPB) is authorized to oversee and conduct all civil and criminal matters arising under the FDCA. See 28 C.F.R. § 0.45(j); [JM 4-1.313](#).

CPB personally handles all civil matters arising under the FDCA, except as provided in [JM 4-8.220](#) as to routine seizure actions. Information relating to a possible civil violation of the FDCA should be brought immediately to CPB's attention.

CPB personally handles, jointly handles, or monitors all criminal matters involving possible violations of the FDCA. Upon opening any criminal investigation involving a possible violation of the FDCA, USAOs must notify and consult with CPB. A USAO conducting such an investigation must also consult with CPB as to what role CPB will play in the investigation. CPB will confirm receipt of and respond to a notification within 15 business days.

CPB generally will personally or jointly handle investigations and cases involving possible criminal violations of the FDCA that it deems to have nationwide implications. Investigations and cases that have nationwide implications may include, but are not limited to, instances in which:

1. a publicly traded corporation is a criminal target or criminal defendant;
2. a non-frivolous First Amendment defense may be available;
3. a subject's or target's individual liability, criminal or civil, is based on the "responsible corporate officer" doctrine (the so-called *Park* doctrine);
4. the conduct at issue led to death or other serious bodily injury;
5. the amount of any criminal fine, forfeiture, disgorgement, and/or restitution or of any related civil damages or penalties may exceed \$100 million; or
6. the conduct at issue involves fraud on or misleading the FDA.

For a monitored criminal investigation or case, CPB may request status updates on the matter's progress and legal and factual theories. At least 15 business days before filing criminal charges in a monitored matter, a USAO must notify and consult with CPB regarding the factual and legal basis for the charges.

Throughout the course of any criminal or civil litigation action concerning alleged FDCA violations or involving the FDA, USAOs are required to report to CPB significant litigation

developments involving FDCA policy and interpretation, questions of first impression concerning the FDCA, and any adverse court decisions construing the FDCA or its implementing regulations.

Attorneys from the FDA may not be appointed as Special Assistant U.S. Attorneys without the approval of CPB's Director.

Notice to CPB is provided through the Director, Deputy Directors, or Assistant Directors (see the directory "Expertise in the Civil Division").

[updated January 2021]

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## **4-8.205 – Litigation Involving Drugs or Medical Devices**

In considering whether to initiate or continue an investigation, civil complaint, or criminal prosecution involving promotion of an unapproved use of an FDA-approved drug or device, the Department will prioritize matters involving promotion that is false, misleading, or encourages unapproved new uses likely to cause consumer harm. In any such matter, Department attorneys also should consult relevant Department resources and note that some courts have held that truthful, non-misleading commercial speech does not itself violate the FDCA.

[updated January 2021]

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## **4-8.215 – Strict Misdemeanor Liability and “Park” Misdemeanor Liability Under the FDCA**

A misdemeanor conviction under the FDCA does not require proof of fraudulent intent, or even of knowing or willful conduct. CPB attempts wherever possible to bring felony charges to deal with fraudulent behavior. Nevertheless, misdemeanor liability can attach to behavior that may not merit felony prosecution. What is more, an individual who stands in responsible relation to the violative conduct, even if he or she did not engage in the conduct itself, may be liable under the “responsible corporate officer” doctrine (the so-called *Park* doctrine).

[updated January 2021]

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## **4-8.220 – FDCA Seizures**

FDA routinely recommends seizure actions under the FDCA (authorized by 21 U.S.C. § 334) by direct referral to USAOs. Most of these actions involve filthy storage conditions at food warehouses and similarly clear FDCA violations. However, some seizure recommendations are based on novel or difficult legal theories. Consultation with CPB as required under JM 4-8.200 will ensure USAOs have access to the most recent guidance.

[updated April 2018]

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## **4-8.225 – Tobacco**

CPB handles tobacco-related litigation in both affirmative and defensive contexts. Typically, defensive cases challenge rulemakings or guidance issued by FDA's Center for Tobacco Products, as well as product-specific determinations relating to the marketing of new tobacco products.

[updated April 2018]

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## **4-8.230 – Defensive FDCA Litigation**

CPB has exclusive authority to defend in federal district courts FDA actions challenged under the Administrative Procedure Act or constitutional provisions. These cases typically come directly to CPB from FDA. USAOs served with a complaint against FDA should notify CPB.

[updated January 2021]

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## **4-8.300 – The FTC Act and Other Statutes Administered by the Federal Trade Commission**

Upon appropriate certification by the Federal Trade Commission ("FTC"), CPB is responsible for the institution of criminal proceedings under the Federal Trade Commission Act (FTC Act) (15 U.S.C. § 56(b)), and for determining whether the Attorney General will commence, defend, or intervene in civil proceedings under the FTC Act (15 U.S.C. § 56(a)). 28 C.F.R. § 0.45(j).

CPB also is responsible for litigation arising under other statutes administered by the FTC, including the Consumer Credit Protection Act (15 U.S.C. §§ 1611, 1681q and 1681r), relating to the disclosure of credit terms; section 11(l) of the Clayton Act (15 U.S.C. § 21(l)) involving violations of orders issued by the Federal Trade Commission; the Fair Debt Collection Practices Act (15 U.S.C. §§ 1692-1692p); the Fair Credit Reporting Act (15 U.S.C. §§ 1681-1681x); the Credit Repair Organizations Act (15 U.S.C. §§ 1679-1679j); the Telemarketing Sales Rule (16 C.F.R. Part 310); the Children's Online Privacy Protection Act (15 U.S.C. §§ 6501-6506); the Restore Online Shoppers' Confidence Act (15 U.S.C. §§ 8401-8405); the Better Online Ticket Sales Act (15 U.S.C. § 45c); and other statutes that protect consumers from unfair and deceptive practices and privacy violations. FTC staff frequently refer matters to CPB for criminal investigation where a civil action by the agency uncovers egregious wrongdoing. CPB also defends actions brought against the FTC.

The Antitrust Division is responsible for bringing civil penalty actions under Section 7A of the Clayton Act, whether they arise from DOJ or FTC investigations. The Antitrust Division handles such cases on behalf of the FTC pursuant to a Memorandum of Understanding, or the DOJ may appoint FTC attorneys as Special Attorneys to file and litigate their own Section 7A cases under DOJ supervision. (Where an FTC investigation of, or civil action concerning, an antitrust violation uncovers conduct warranting criminal investigation or prosecution under the antitrust or related statutes, the FTC refers the matter to the Antitrust Division, see generally JM Title 7: Antitrust. With approval from the Antitrust Division, USAOs can also investigate and prosecute under the antitrust statutes either alone or jointly with the Antitrust Division).

[updated January 2021]

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## **4-8.400 – Elder Fraud, Servicemember Fraud, and other Mass-Marketing Fraud Schemes**

CPB regularly prosecutes large-scale criminal and civil cases involving domestic and international consumer fraud schemes. CPB devotes particular attention to stopping scams that disproportionately target or affect older Americans, including through its coordination of the Department's Transnational Elder Fraud Strike Force. CPB has particular expertise in bringing civil injunctive actions under 18 U.S.C. § 1345 to stop ongoing consumer frauds. CPB is available to partner with, provide guidance, and offer resources to USAOs.

CPB also advances the Department's Servicemembers and Veterans Initiative by investigating and prosecuting fraud targeting U.S. servicemembers and veterans.

[updated January 2021]

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## **4-8.500 – The Consumer Product Safety Act and Other Statutes Administered by the Consumer Product Safety Commission**

CPB is responsible for civil and criminal litigation and grand jury proceedings arising under the Consumer Product Safety Act (15 U.S.C. § 2051 et seq.), which authorizes the CPSC to pursue recalls and requires manufacturers to report dangerous products. CPB also is responsible for litigation under the Federal Hazardous Substances Act (15 U.S.C. § 1261 et seq.), which requires warning labels on hazardous products and empowers the CPSC to ban products where a label would not adequately protect consumers; the Poison Prevention Packaging Act (15 U.S.C. § 1471 et seq.), concerning child-resistant packaging; and the Flammable Fabrics Act, relating to flammable clothing and interior furnishings (15 U.S.C. § 1191 et seq.). 28 C.F.R. § 0.45(j).

CPB is responsible for determining under the Consumer Product Safety Act (15 U.S.C. § 2076(b)(7)), whether the Attorney General will initiate, prosecute, defend, or appeal actions relating to the CPSC. 28 C.F.R. § 0.45(j). Matters relating to the CPSC are referred directly to CPB. CPB also defends actions brought against the CPSC.

[updated January 2021]

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## 4-8.600 – Statutes Administered by the National Highway Traffic Safety Administration

CPB is primarily responsible for civil and criminal litigation and grand jury proceedings arising under the Automobile Information Disclosure Act (15 U.S.C. § 1231 et seq.), as well as the odometer requirements section and the fuel economy labeling section of the Motor Vehicle Information and Cost Savings Act (15 U.S.C. § 1981 et seq.). 28 C.F.R. § 0.45(j). USAOs should contact CPB when an investigation is opened under one of these statutes. In general, unless a USAO requests more active assistance on such investigations, CPB will merely monitor opened investigations. USAOs should provide CPB a copy of any proposed indictment or information charging a crime under the statutes at least two weeks before presentation or filing.

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## 4-8.700 – Civil Penalty and Injunctive Actions

CPB brings injunction suits, declaratory judgment actions, applications for inspection warrants, and cases seeking civil penalties to enforce government rights, functions, and monetary claims in matters involving consumer safety and regulated products. See, e.g., 28 C.F.R. § 0.45(h), (j); [JM 4-1.313](#).

[added January 2021]

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[< 4-7.000 - Immigration Litigation](#)

[4-9.000 - Financial Litigation Policy >](#)



**U.S. Department of Justice**

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