Administrative law research

April 1, 2008
Melanie Dunshee
Agenda

- Where regulations come from
  Delegation doctrine
- Rules and regulations
  process, publication, tracing history
- Monitoring regulatory activities
- Agency judicial materials
- Finding administrative materials
  LexisNexis/Westlaw strengths
  specialized services – CCH
  Agency websites
Delegation

- Legislative power given to Congress in the U.S. Constitution
- Congress delegates its lawmaking authority to an agency (enabling legislation)
- Justifications:
  - More flexible and quicker action
  - Combination of legislative, executive, and judicial solutions
Examples

- **15 USC 45**
  - (a) Declaration of unlawfulness; power to prohibit unfair practices
  - (a) Declaration of unlawfulness; power to prohibit unfair practices; inapplicability to foreign trade
    (1) Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.
  - (2) The Commission is hereby empowered and directed to prevent persons, .... from using unfair methods of competition in or affecting commerce and unfair or deceptive acts or practices in or affecting commerce.

- **15 USC 57a**
  - (a) Authority of Commission to prescribe rules and general statements of policy
    - (1) Except as provided in subsection (h) of this section, the Commission may prescribe--
      - (A) interpretive rules and general statements of policy with respect to unfair or deceptive acts or practices in or affecting commerce (within the meaning of section 45(a)(1)of this title), and
      - (B) rules which define with specificity acts or practices which are unfair or deceptive acts or practices in or affecting commerce (within the meaning of section 45(a)(1)of this title), except that the Commission shall not develop or promulgate any trade rule or regulation with regard to the regulation of the development and utilization of the standards and certification activities pursuant to this section. Rules under this subparagraph may include requirements prescribed for the purpose of preventing such acts or practices.
12 USC § 371. Regulations and hearings

(a) Authority to promulgate regulations

The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

(b) Regulations for imports and exports

The Secretary of the Treasury and the Secretary of Health and Human Services shall jointly prescribe regulations for the efficient enforcement of the provisions of section 381 of this title, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Health and Human Services shall determine.

(c) Conduct of hearings

Hearings authorized or required by this chapter shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

........

(h) Guidance of documents

(1)(A) The Secretary shall develop guidance documents with public participation and ensure that information identifying the existence of such documents and the documents themselves are made available to the public both in written form and, as feasible, through electronic means. Such documents shall not create or confer any rights for or on any person, although they present the views of the Secretary on matters under the jurisdiction of the Food and Drug Administration.
Wild Bird Conservation Act

- **16 USC § 4904. Moratoria on imports of exotic birds covered by Convention**
  - (2) Termination of moratorium
    A species of exotic birds shall be subject to the prohibition on importation established by paragraph (1) until the Secretary, after notice and an opportunity for public comment--
    - (A) determines that appropriate remedial measures have been taken in the countries of origin for that species, so as to eliminate the threat of trade to the conservation of the species; and
    - (B) makes the findings described in section 4905(c) of this title for the species and includes the species in the list published under section 4905(a) of this title.

- **16 USC § 4905. List of approved species**
  - (a) Listing
    - (1) In general
    One year after October 23, 1992, and periodically thereafter, the Secretary shall, after notice and an opportunity for public comment, publish in the Federal Register a list of species of exotic birds that are listed in an Appendix to the Convention and that are not subject to a prohibition or suspension of importation otherwise applicable under section 4904(a), (b), or (c) of this title.

  - (2) Manner of listing
    The Secretary shall list a species under paragraph (1) with respect to--
    - (A) the countries of origin from which the species may be imported; and
    - (B) if appropriate, the qualifying facilities in those countries from which the species may be imported.
Rulemaking

- Administrative Procedures Act, 5 U.S.C. 553 procedural process for implementing legislative power
- Notice and Comment (informal rulemaking)
  - publication of proposed rules
  - period for comments and participation in the decision making
  - publication of final rule
- same force of law as legislation
Other administrative materials

- Guidelines, guidance documents
- Policy statements on how agency intends to act
- Interpretations, agency view of what the law requires
- Investigation, fact gathering
- Enforcement activities and quasi-judicial functions

Varies by agency
Publication of regulatory materials

- **Federal Register (FR)**
  daily publication for all agency activities
  LexisNexis and Westlaw – July 1980 –
  HeinOnline – 1936 – (use freely in summer with NetID)
  GPO Access – 1994 – always free

- **Code of Federal Regulations (CFR)**
  compilation of final regulations in force
  LexisNexis and Westlaw – 1980 – (note currency)
  HeinOnline - 1938 - (use freely in summer with NetID)
  GPO Access – 1996 – browse and search
  e-CFR – currently updated version
Code of Federal Regulations – Titles

1 – General Provisions
2 – Grants and Agreements
3 – The President
4 – Accounts
5 – Administrative Personnel
6 – Homeland Security
7 – Agriculture
8 – Aliens and Nationality
9 – Animals and Animal Products
10 – Energy
11 – Federal Elections
12 – Banks and Banking
13 – Business Credit and Assistance
TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER C--DRUGS: GENERAL

PART 208  MEDICATION GUIDES FOR PRESCRIPTION DRUG PRODUCTS

Subpart A--General Provisions
§ 208.1 - Scope and purpose.
§ 208.3 - Definitions.

Subpart B--General Requirements for a Medication Guide
§ 208.20 - Content and format of a Medication Guide.
§ 208.24 - Distributing and dispensing a Medication Guide.
§ 208.26 - Exemptions and deferrals.

Source: 63 FR 66396, Dec. 1, 1998, unless otherwise noted.
Tracing Regulation History

- Similar to legislative history
- Federal Register contains explanations of agency process, summaries of comments, changes with final regulation
§ 1.20 Presence of mandatory label information.
Effective: [See Federal Register] Prior
Approx. 1 page

(d) Containers used for tray pack displays in retail establishments.

(e) Transparent wrappers or containers which do not bear written, printed, or graphic matter obscuring the label information required by this part.

A requirement contained in this part that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or information also appears on the outer container or wrapper of the retail package of the article, or, as stated in paragraph (e) of this section, such information is easily legible by virtue of the transparency of the outer wrapper or container. Where a consumer commodity is marketed in a multiunit retail package bearing the mandatory label information as required by this part and the unit containers are not intended to be sold separately, the net weight placement requirement of § 101.105(f) applicable to such unit containers is waived if the units are in compliance with all the other requirements of this part.


United States Code Annotated Currentness
Title 21. Food and Drugs (Refs & Annos)

Subchapter III. Prohibited Acts and Penalties

§ 331. Prohibited acts

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 344, 355, or 360b-bb-3 of this title.

(e) The refusal to permit access to or copying of any record as required by section 350a, 350b, 350g, 351, 352, 352c, 353, 353a, 353b, 353c, 353d, 353e, 353f, 353g, 353h, 353i, 353j, 353k, 353l, 353m, 353n, 353o, 353p, 353q, 353r, 353s, 353t, 353u, 353v, 353w, 353x, 353y, 353z, 353aa, 353bb, 353cc, 353dd, 353ee, 353ff, 353gg, 353hh, 353ii, 353jj, 353kk, 353ll, 353mm, 353nn, 353oo, 353pp, 353qq, 353rr, 353ss, 353tt, 353uu, 353vv, 353ww, 353xx, 353yy, 353zz, or 388 of this title.
location where the requirements of this AD can be done.

Effective Date

(j) This amendment becomes effective on January 23, 2002.

Issued in Burlington, Massachusetts, on December 7, 2001.

Jay J. Pardon,
Manager, Engine and Propeller Directorate,
Aircraft Certification Service.

[FR Doc. 01-30952 Filed 12–18–01; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 98N–0583]

Exports: Notification and Recordkeeping Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) received 18 comments on the proposed rule. In addition, the agency received several comments on the export notification and recordkeeping discussions in its draft export guidance document which was published in the Federal Register on June 12, 1998 (63 FR 32219, FDA docket number 98D– 0307). Drug manufacturers, device manufacturers, device exporters, and food, drug, and device trade associations submitted comments. An animal drug trade association and a biological product company also submitted comments. Because FDA wrote both the proposed rule and the guidance document contemporaneously, the agency considered comments submitted on the proposed rule and related comments submitted on the draft export guidance document when it prepared this final rule.

II. Comments on the Proposed Rule. Including Related Comments Submitted to the Draft Guidance Document

Most comments focused on specific provisions in the proposed rule. However, others made general comments about FDA’s export authority or the need for any regulations or
Monitoring developments

- Daily table of contents
  - GPO Access
  - Westlaw – FR-TOC

- Alert services
  - Westlaw – Agency Tracker – email
  - LexisNexis – Federal Regulation Tracking
  - CCH databases
The Federal Register Collection / Code of Federal Regulations

Access the Most Current Federal Register Day on the GPO Website

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- **Volume 66**
  - 2001
Federal Register
Online via GPO Access

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Decisions and Rulings

- Hearings and decisions by administrative law judges NOT published in FR, but may be referenced there
- About 15 agencies officially report decisions (Bluebook T.1)
- UVA list
- HeinOnline – US Federal Agency Library
- LexisNexis and Westlaw
  NOT in notes of decisions in Code, but look for links
Finding and discovery

- Code does not usually connect with its related regulations
  - But recently more Westlaw and LexisNexis links
- Search CFR independently of statute (LexisNexis/Westlaw, GPOAccess)
- Usual techniques of secondary sources, references in cases
- Specialized research tools (e.g. CCH, BNA)
- Agency websites
The Congress finds the following:

Go to the United States Code Service Archive Directory

16 USCS § 4901

4901. Findings
16 USCS § 4905

Retrieve Legislative Impact?

UNITED STATES CODE SERVICE
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*** CURRENT THROUGH P.L. 110-198, APPROVED 3/24/2008 ***

TITLE 16. CONSERVATION
CHAPTER 59. WILD EXOTIC BIRD CONSERVATION

Go to the United States Code Service Archive Directory

4905. List of approved species

1) Listing.
FOR EDUCATIONAL USE ONLY

16 U.S.C.A. § 4901

United States Code Annotated  Currentness
Title 16. Conservation
Chapter 69. Wild Exotic Bird Conservation

§ 4901. Findings

The Congress finds the following:

(1) In addition to habitat loss and local use, the international pet trade in wild-caught exotic birds is contributing to the decline of species in the wild, and the mortality associated with the trade remains unacceptably high.

(2) The United States, as the world’s largest importer of exotic birds and as a Party to the Convention, should play a substantial role in finding effective solutions to these problems, including assisting countries of origin in implementing programs of wild bird conservation, and ensuring that the market in the United States for exotic birds does not operate to the detriment of the survival of species in the wild.

(3) Sustainable utilization of exotic birds has the potential to create economic value in the
§ 4901, Findings

Effective: [See Text Amendments]

- 28 50 CFR s 14.11; s 14.11 General restrictions
- 29 50 CFR s 14.12; s 14.12 Designated ports.
- 32 50 CFR s 14.15; s 14.15 Personal baggage and household effects.
- 33 50 CFR s 14.16; s 14.16 Border ports.
- 34 50 CFR s 14.17; s 14.17 Personally owned pet birds.
- 35 50 CFR s 14.18; s 14.18 Marine mammals.
- 36 50 CFR s 14.19; s 14.19 Special ports.
- 37 50 CFR s 14.20; s 14.20 Exceptions by permit.
- 38 50 CFR s 14.21; s 14.21 Shellfish and fishery products.
- 40 50 CFR s 14.23; s 14.23 Live farm-raised fish and farm-raised fish eggs.
- 42 50 CFR s 14.31; s 14.31 Permits to import or export wildlife at nondesignated port for scientific purposes.
§ 4905. List of approved species
Effective: [See Text Amendments]

- **2** 50 CFR s 15.2; s 15.2 Scope of regulations.
- **3** 50 CFR s 15.3; s 15.3 Definitions.
- **4** 50 CFR s 15.4; s 15.4 Information collection requirements.
- **5** 50 CFR s 15.11; s 15.11 Prohibitions.
- **6** 50 CFR s 15.12; s 15.12 Requirements.
- **7** 50 CFR s 15.21; s 15.21 General application procedures.
- **8** 50 CFR s 15.22; s 15.22 Permits for scientific research.
- **9** 50 CFR s 15.23; s 15.23 Permits for zoological breeding or display programs.
- **10** 50 CFR s 15.24; s 15.24 Permits for cooperative breeding.
- **11** 50 CFR s 15.25; s 15.25 Permits for personal pets.
- **12** 50 CFR s 15.26; s 15.26 Approval of cooperative breeding programs.
- **13** 50 CFR s 15.31; s 15.31 Criteria for including species in the approved list for captive-bred species.
- **14** 50 CFR s 15.32; s 15.32 Criteria for including species in the approved list for non-captive-bred species.
- **15** 50 CFR s 15.33; s 15.33 Species included in the approved list.