Update

Author Style Sheet

TEXT STYLE

GENERAL RULES:

- Word counts (including references):
    - Features: 1,500-2,500
    - Nonfeatures: 1,000-2,000
    - Letters to the Editor: 500
    - Columns:
        - Associates' Corner: 1,000
        - Enforcement: 1,000
        - Global: 1,000
        - History: 1,000

- Keep paragraphs short and use subheads to break up text.
- Extensive referencing is not required for *Update*. References should be presented as endnotes.
- Affiliation information should include current title, company or organization, and location. When relevant to the subject matter of the article, include a single sentence statement of interest or past position.
- Third person (versus first person or overly "speechified") grammatical form is preferred, unless the piece is being reproduced from a speech and/or there is express author preference for such.
- There is **only one space** between the punctuation at the end of one sentence and the start of a new sentence.
- Do not use "the" before FDA when referring to the agency as a noun.
- Do not use contractions.
- In text, it is generally preferred to spell out a word in full (e.g., advertisements, **not** ads).
- Delete or strip out of the document any "sophisticated" wordprocessing coding and/or complex formatting. Use "straight text" – all in one size and type of font; no internal outlining or Word coding/formatting/macros/etc.; no "styles" applied to the document; and all "images" (e.g., charts, tables, graphs, figures, etc.) must be legible and electronic files suitable for transfer and layout.

ABBREVIATIONS & ACRONYMS:

- Only use acronyms for phrases that are used more than once in an article or chapter.
- When referring to a statute (like the Federal Food, Drug, and Cosmetic Act), it is generally preferred that the shortened form be referred to as an acronym (FDCA). Refer to a statute as "the Act" only when one statute is discussed.
- Spell out the full phrase followed by the acronym in parentheses the first time it appears in the text; thereafter refer only to acronym.
- When using a possessive, put the apostrophe into the acronym. [**Example:** Food and Drug Administration's (FDA's) policy."

- Use “United States” when using the noun form, but “U.S.” when using it as an adjective.
- It is permissible to use acronyms in titles and subheads, unless the words need to be spelled out for clarity.

CAPITALIZATION:

- When referring to FDA or any other government administrative body, do not capitalize “agency,” “department,” “board,” “bureau,” “commission,” “administration,” etc. unless that word is a part of its formal title.
- Use lower case “c” for congressional but upper case “c” for Congress.
- Do not capitalize “federal,” “government,” or “court” (unless the reference is to the U.S. Supreme Court or it is used in the full title of a court, such as the “Tenth Circuit Court of Appeals”).
- In headings, titles, and article subheads, capitalize the initial word, the word immediately following a colon, and all other words except the articles “a, an, the”; the conjunctions “and, as, but, if, or, nor”; and the prepositions “at, by, for, in, of, on, to.”
- Technical terms: Internet and Web, but website, e-mail, and online.

ITALICIZING:

- Do not italicize “e.g.” or “i.e.” in text.
- Italicize the names of publications, including *Federal Register, Code of Federal Regulations, United States Code, Congressional Record, U.S. Code Congressional & Administrative News, Restatement (2d and 3d, etc.) of Torts,* hearing titles, etc. Do not italicize FDA Compliance Policy Guides.
- Italicize the names of court cases that appear in text and article titles, but do not italicize case names in subheads.
- Italicize words in foreign language (Latin, etc.) **only** if word is not commonly used/understood in English. Use the dictionary as a guide. If a foreign or Latin word appears in an English dictionary, it need not be italicized. **Examples:** mea culpa, a priori, et al., in vitro, etc.

HYPHENATION:

- Hyphenate blended words when prefix ends in a vowel (“pre”) and root starts with a vowel (“approval”): pre-approval.
- Do not hyphenate when vowels bump consonants (“premarket”) or consonants bump consonants (“postmarket”).
- Hyphenate descriptive words used together as adjectives (e.g., “well-controlled study” or “FDA-regulated product”).
- Preference is away from hyphens in the spelling of compound words; use one-word construction when meanings are clear. **Examples:** website, healthcare, online, and worldwide. **Exception:** e-mail.

NUMBERS:

- Numbers should be spelled out in text and footnotes from zero to nine. 10 and up should be in numerals in text and footnotes—unless sentence begins with a number.

- Use bullets to list items if possible. If numbers or letters must be used to list items, they should be placed in open and closed parentheses (e.g., (1) or (a)).
- If items are listed in a sentence numerically or alphabetically, the number or letter should be followed only by a closed parentheses (e.g., 1) ... 2)... and 3)...). Either commas or semicolons may be use after each item, depending on usage.
- Numbers listed consecutively in a sentence should be listed numerically, no matter the size (e.g., "10 mg, 200 mg, and 1,000 mg doses").
- Four-digit or more numbers should use a comma (e.g., 1,400 or 6,325,988).

PUNCTUATION:

- Use semi-colons to separate clauses that contain commas and to link related, but otherwise independent, clauses. If a conjunction is used between independent phrases, use a comma and **not** a semi-colon.
- Apostrophe should be placed alone at the end of words ending in "s" to show possessive (e.g., Congress' and agencies' actions). Do not use an apostrophe when making nouns plural, not possessive (e.g., GMPs not GMP's).
- Use a comma before "and" or "or" in a series of three or more (e.g., one, two, and three).
- An ellipsis—the omission of a work, phrase, line, paragraph, or more from a quoted passage—must be indicated by ellipsis points or dots.
- There is no space before and after an em dash.
- The abbreviation "e.g." means "for example." The abbreviation "i.e." means "that is."

FOOTNOTE STYLESHEET INFO

- Do not use underline to indicate italics.
- In titles of periodicals and for multiple authors in footnote/citations, "and" should be indicated by ampersand (&).
- When using three-digit number ranges, in footnote number references or page nos., drop first digit of end-range number, unless it's misleading to do so: Use "125-29," but use "195-203".
- Do not place <> around URLs. **Example:** www.fdli.org **not** <www.fdli.org>. Add a last visited date after the URL. Example: www.fdli.org (last visited June 11, 2002)

Examples of *Bluebook* citation:

- **AGENCY MATERIALS**: U.S. Department of Agriculture (USDA), Food Recovery and Gleaning Initiative Fact Sheet (1998), *available at* www.fns.usda.gov/FNS/MENU/GLEANING/RECOVER.HTM (last visited Jan. 1, 2002).
    - Centers for Disease Control and Prevention (CDC), Guideline for the Use of Antiretroviral Agents, *available at* www.cdc.gov/mmwr/PDF/rr/rr4704.pdf (last visited Feb. 19, 2002).
    - Panel on Clinical Practices for the Treatment for the Treatment of HIV Infection, convened by Dep't of Health and Human Serv. and Henry J. Kaiser Family Foundation, Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults & Adolescents (Feb. 4, 2002) [hereinafter DHHS Antiretroviral Agent Guidelines], *available at* www.hivatis.org/guidelines/adult/Feb04_/AdultGdl.pdf (last visited Feb. 23, 2002).
    - UNAIDS AND WORLD HEALTH ORGANIZATION (WHO), AIDS EPIDEMIC UPDATE (Dec. 2001), *available at* www.unaids.org/epidemic_update/report_dec01/ (last visited Feb. 18, 2002).
    - WHO, REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC (June, 1998), *available at* www.who.int/emc_hiv/global_report/rep_html/reprt2.html (last visited Feb. 18, 2002).

- **ADMINISTRATIVE MATERIALS**: Medical Devices; Current Good Manufacturing Practice Final Rule; Quality System Regulation, 61 Fed. Reg. 52,602, 52,610 (Oct. 7, 1996).
    - Center for Devices and Radiological Health (CDRH), FDA, Draft Guidance, Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme (Feb. 8, 2000), at 1, *available at* www.fda.gov/cdrh/reuse/1156.html (last visited Oct. 5, 2001) [hereinafter RPS Guidance Document].

- **BOOKS**: J. GREGORY SIDAK & DANIEL F. SPULBER, DEREGULATORY TAKINGS AND THE REGULATORY CONTRACT 102 (1998).
    - Giuseppa Pantaleo et al., *Immunopathogenesis of Human Immunodeficiency Virus Infection*, *in* AIDS: BIOLOGY, DIAGNOSIS, TREATMENT & PREVENTION 75-88 (Vincent T. DeVita et al., eds., 4th ed. 1997).

- **CASES**: Serono Labs. v. Shalala, 35 F. Supp. 2d 1, 2 (D.D.C. 1999); Zeneca, Inc. v. Shalala, Food Drug Cosm. L. Rep. (CCH) 38,581 (D. Md. 1999).

- **HEARINGS**: *H.R. 2428. The Good Samaritan Food Donation Act: Hearing Before the House Subcomm. on Postsecondary Educ., Training, and Life-long Learning of the Comm. on Econ. and Educ. Opportunities*, 104th Cong. 10 (1996) (statement of Christine Vladimiroff, President, America's Second Harvest) [hereinafter *1996 Hearing*].

- **LETTERS**: Letter from Anne Berdahl, Assistant Vice-President, Federation of American Health Systems, to Larry Spears, Office of Human Resources and Management Services, Division of Management System and Policy, FDA, (Apr. 11, 2000), *available at* www.fda.gov/ohrms/dockets/dailys/00/apr00/042800/c000031.pdf (last visited Oct. 15, 2001).

- **MAGAZINES**: Peter Mansell, *Is Industry Losing Its Grip on Rx-to-OTC Switching?*, SCRIP MAGAZINE, Apr. 2002, at 6; Bill Bailey, *New Drugs Coming*, F-D-C REP. ("The Pink Sheet"), May 6, 2002, at 9.

- **NEWSPAPERS**: Richard Benke, *Despite Economy, Hunger Remains*, BOSTON GLOBE, Dec. 14, 2000, at A9.

- **PERIODICALS**: See Janice M. Hogan & Thomas E. Colonna, Products Liability Implications of Reprocessing and Reuse of Single-Use Medical Devices, 53 FOOD DRUG L.J. 385, 386-97 (1998). Tom Copmann & Gregory Davis et al., One Product, One Process, One Set of Specifications, 25 PHARMACEUTICAL TECH. 26 (Mar. 2001).

- **PRESS RELEASES**: Press Release, Centers for Disease Control and Prevention (CDC), States Receive $40 Million for Stronger Public Health Preparedness for Bioterrorism (Sept. 15, 1999) *available at* www.cdc.gov/od/oc/media/pressrel/r990915.htm (last visited Mar. 15, 2002).

- **REGULATIONS**: Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices, 21 C.F.R. § 807 (1999).

- **STATUTORY MATERIAL**: Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (codified at 21 U.S.C. §§ 301 note, 321, 333, 333 note, 351, 353, 360, 360c, 360c note, 360d-360i, 360i notes, 360j, 360j note, 360*l*, 360gg-360hh, 360hh note, 360ii-360ss, 383, 383 note (1994)); 42 U.S.C. §§ 263b-263n (1994)); Food and Drug Administration Modernization Act of 1997 (FDAMA), Pub. L. No. 105-115, 111 Stat. 2295 (amending 21 U.S.C. §§ 301 et seq. (1994)); 21 U.S.C. § 355(b)(2).

    - If an act has a year in its formal title/name ("Nutrition Labeling and Education Act of 1990"), do not put year in parens in the citation
    - When citing the FDCA, do not use the Pub. L. No. each time; reference the relevant U.S.C. section, with a parallel to the FDCA section. (21 U.S.C. § ____ (FDCA § ____)).

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