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BY FEDERAL EXPRESS

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: **Docket No. 2005P-0436:**
NDA 21-863; Ibuprofen Liquid Filled Gelatin
Capsules 200 mg; Ranbaxy Laboratories Ltd.

SUPPLEMENT TO CITIZEN PETITION

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The undersigned, on behalf of Banner Pharmacaps Inc. of High Point, North Carolina, submits this Supplement to the above-referenced Citizen Petition (dated October 27, 2005; docketed October 28, 2005), responding to the comments on the Petition filed by Buc & Beardsley on behalf of Ranbaxy Laboratories Ltd. (dated February 22, 2006; docketed February 28, 2006).

I. Ranbaxy Disregards the Impact of FDA's 505(b)(2) Fenofibrate Ruling

Not surprisingly, Ranbaxy's comments disregard the manifest impact on this case of FDA's November 30, 2004 ruling regarding a Section 505(b)(2) NDA for the drug fenofibrate (Docket No. 2004P-0386, Ruling on Abbott Laboratories Citizen Petition; see Banner's original Citizen Petition herein, Exhibit I). In that precedential ruling, FDA articulated the standards by which a Section 505(b)(2) NDA applicant must address Orange Book patents for the drug product for which it seeks regulatory approval.

The fenofibrate ruling devotes an entire section to the matter of what listed drug (or listed drugs) a 505(b)(2) applicant must rely upon for purposes of patent certification. The section bears repeating in pertinent part:

"C. Choosing the Listed Drug

In contrast to Abbott's sweeping approach to identifying listed drugs for

2005P-0436

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patent certifications, FDA's approach is tailored more narrowly to reflect the logic and language of the statute. Given that a 505(b)(2) applicant must certify only to patents on the listed drug relied on for approval, each proposed 505(b)(2) application must identify the listed drug or drugs on which it seeks to rely. Once a listed drug has been identified, the 505(b)(2) applicant need only provide sufficient information to support any change from the listed drug proposed (21 CFR 314.54(a)). FDA's Draft Guidance for Industry, *Applications Covered by Section 505(b)(2)* (Draft Guidance), makes clear, however, that **'[i]f there is a listed drug that is the pharmaceutical equivalent¹¹ [of] the drug proposed in the 505(b)(2) application, that drug should be identified as the listed drug'** (Draft Guidance at 8). It further provides that **'if there is a listed drug that is the pharmaceutical equivalent of the drug proposed in the 505(b)(2) application, the 505(b)(2) applicant should provide patent certifications for the patents listed for the pharmaceutically equivalent drug'¹²** (Draft Guidance at 8). These provisions ensure that the 505(b)(2) applicant **does not use the 505(b)(2) process to end-run patent protections that would have applied had an ANDA been permitted.**¹³ They further ensure that **the 505(b)(2) applicant (and FDA) can rely, to**

¹¹ "FDA's regulations at 21 CFR 320.1(c) define pharmaceutical equivalents as:

drug products in identical dosage forms that contain identical amounts of the identical active drug ingredient, i.e., the same salt or ester of the same therapeutic moiety, or, in the case of modified release dosage forms that require a reservoir or overage or such forms as prefilled syringes where residual volume may vary, that deliver identical amounts of the active drug ingredient over the identical dosing period, do not necessarily contain the same inactive ingredients; and meet the identical compendia or other applicable standard of identity, strength, quality and purity, including potency and, where applicable, content uniformity, disintegration times, and/or dissolution rates (emphasis supplied)."

¹² A 505(b)(2) application may be submitted for a pharmaceutical equivalent to a previously approved drug product when, for example, the 505(b)(2) contains a novel excipient that requires a safety study and therefore cannot be approved in an ANDA. FDA regulations establish, however, that FDA may refuse to file a 505(b)(2) application eligible for approval under section 505(j) (21 CFR 314.101(d)(9)).

¹³ Similarly, if a tablet and a capsule are approved for the same moiety with patents listed for the tablet and none listed for the capsule, an ANDA applicant seeking approval for a tablet should cite the approved tablet as the reference listed drug. **It should not circumvent the patents on the tablet by citing the capsule as the reference listed drug** and filing a suitability petition under section 505(j)(2)(C) of the Act and 21 CFR 314.93 seeking to change to a tablet dosage form (emphasis supplied)."

the maximum extent possible, on what is already known about a drug without having to re-prove (or re-review) what has already been demonstrated. See 505(b)(2) Petition Response at 3 ('FDA's longstanding interpretation of section 505(b)(2) is intended to permit the pharmaceutical industry to rely to the greatest extent possible under the law on what is already known about a drug')... ”

(Fenofibrate Ruling, Nov. 30, 2004, pp. 8-9, emphasis supplied).

Accordingly, FDA's Section 505(b)(2) Guidance and fenofibrate ruling teach:

- There can be **more than one listed drug** upon which a 505(b)(2) applicant is **required to rely**.
- The 505(b)(2) applicant **must rely** on any listed drug that is the **pharmaceutical equivalent** of the drug for which the applicant is seeking approval.
- This is so **even if** there is another listed drug upon which the 505(b)(2) applicant seeks to rely for safety and efficacy data.

II. Ranbaxy Was Compelled To Reply Upon Banner's Pharmaceutically Equivalent Drug Product

Under the above principles, Ranbaxy had no choice. It was compelled to rely upon Banner's liquid filled gelatin capsules 200 mg containing ibuprofen in free acid form, because Banner's product is the only drug product listed in the Orange Book: (a) containing ibuprofen in free acid base as the active ingredient, (b) in a liquid filled gelatin capsule dosage form, and (c) with a strength of 200mg.* As FDA stated in the fenofibrate ruling, this principle allows the agency to apply to Banner's NDA, "to the maximum extent possible, what is already known about a drug without having to re-prove (or re-review) what has already been demonstrated." (See p. 2, *supra*; Exhibit I to original Citizen Petition herein, p. 9).

Manifestly, Ranbaxy seeks to bypass Banner's NDA, contending that it need only refer FDA to the safety and efficacy data in Wyeth's NDA (Ranbaxy

* Wyeth's drug product contains ibuprofen in combination with potassium salt as the active ingredient, so that Wyeth's product is not pharmaceutically equivalent to Ranbaxy's drug product.

comments, at 5). Yet by seeking approval of a drug product containing the very active ingredient in Banner's product, Ranbaxy of necessity is asking FDA to also consider what is already known by the agency about that active ingredient, in the same dosage form and strength, previously submitted in Banner's NDA. Mere reliance on Wyeth's data is not enough; Ranbaxy selected a particular ibuprofen active ingredient that only Banner's drug product includes. Reliance as well on Banner's NDA is mandatory to fill this gap.**

Banner's claim that Banner's NDA may be ignored because Banner's product is indicated for pain, not migraine headache (Ranbaxy comments, p. 5) is specious. The pain for which Banner's drug product is indicated explicitly includes headache pain. Moreover, a drug product's indication is not a criterion for patent certification in the statute, FDA's regulations, or the Section 505(b)(2) Guidance.

III. Ranbaxy Clearly Attempted To Avoid Banner's Patent

Nor does Ranbaxy credibly argue that the Section 505(b)(2) Guidance and the fenofibrate ruling are inapplicable because Ranbaxy "did not choose from among several possible listed drugs or base its decision on patent-related considerations." (Ranbaxy comments, pp. 4-5). By its own admission, Ranbaxy's original application contained no patent certification; it did not certify against Banner's '426 patent until forced to do so by FDA. (Ranbaxy comments, p. 2). Then Ranbaxy sought to withdraw that certification, but only after it was sued for patent infringement by Banner. *Id.* Ranbaxy even went *ex parte* to FDA to try to get the agency's acquiescence in this unorthodox move. *Id.* Without question, Ranbaxy engaged in blatant gamesmanship to avoid certification against an Orange Book patent for the pharmaceutically equivalent listed drug.

IV. FDA's Interpretation of Section 505(b)(2) Is Both Permissible and Reasonable

Ranbaxy questions FDA's interpretation of Section 505(b)(2) articulated in the 505(b)(2) Guidance and the fenofibrate ruling as not reflective of the statute. (Ranbaxy comments, pp. 4-5).

Not so. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(2), provides that a Section 505(b)(2) applicant must make a patent certification for

** Unlike Ranbaxy here, in the fenofibrate situation the 505(b)(2) applicant did not seek approval of the pharmaceutical equivalent of any listed drug, so there was no gap to fill.

Orange Book patents claiming a listed drug that is the subject of studies relied upon by the applicant which it did not conduct nor obtain a right of reference. FDA's regulations provide the same thing. 21 C.F.R. § 314.50(i)(1)(i)(A). In its Section 505(b)(2) Guidance and the fenofibrate ruling, FDA further interpreted the statute and regulations to require a 505(b)(2) applicant to rely upon a pharmaceutically equivalent listed drug product (even if it also relies upon safety and efficacy data for another non-pharmaceutically equivalent listed drug), to allow FDA to refer to previously-filed data on the pharmaceutically equivalent product when reviewing the 505(b)(2) applicant's NDA. FDA's interpretation is permissible, entirely reasonable, and entitled to deference. *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984); *United States v. Mead Corporation*, 533 U.S. 218 (2001).***

Additionally, the judicial decisions cited by Ranbaxy (comments, p. 5) are inapposite, since none of the holdings involved the issue of patent certification by a Section 505(b)(2) NDA applicant.

V. Ranbaxy's Attempt to Discredit the Section 505(b)(2) Guidance Is Meritless

The criticism that the Section 505(b)(2) Guidance was issued in draft form (Ranbaxy comments, p. 5) can be rejected out of hand. FDA has issued many guidance documents applicable to drug products in draft form, and has applied them as so issued. (See attached excerpt from CDER's Guidance Documents webpage). Industry has relied upon such draft guidances as the agency's interpretation and policy regarding the statute and regulations, until pertinent final guidances are subsequently issued.

VI. The Guidance and Fenofibrate Ruling Fulfill Hatch-Waxman

Finally, contrary to Ranbaxy's assertion (comments, pp. 5-6), the Section 505(b)(2) Guidance and the fenofibrate ruling plainly fulfill the Hatch-Waxman's carefully-crafted compromise requiring certification against applicable patents. The contention that Banner can sue for patent infringement once Ranbaxy's product is on the market (Ranbaxy comments, p. 6) ignores Congress' intent, expressly

*** For FDA to retreat from this interpretation (relied on by the drug industry since the Section 505(b)(2) Guidance issued in 1999), and now adopt Ranbaxy's diametrically-opposed position, would be a marked departure from agency precedent that could not be reconciled by FDA without renouncing its prior statutory interpretation.

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incorporated in Hatch-Waxman, that pertinent patent issues be litigated while the 505(b)(2) applicant's product is being reviewed by FDA before regulatory approval, not after. (See 21 U.S.C. § 355(c)(3)(C)). Furthermore, Hatch-Waxman balance is achieved by requiring a Section 505(b)(2) applicant to make a certification with respect to an Orange Book patent that the applicant would have been required to certify to if the drug product involved had been applied for via an ANDA. (See p. 2, *supra*, and original Petition herein, Exhibit I, p. 9).

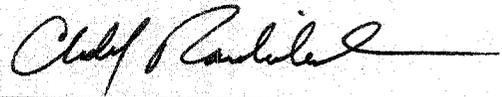
VII. Conclusion

For the reasons set forth in its original Citizen Petition and in this Supplement, Banner's Petition should be granted in its entirety.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP

By



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Guidance Documents

Guidance documents represent the Agency's current thinking on a particular subject. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. For information on a specific guidance document, please contact the originating office.

Most of these documents are in Adobe Acrobat format , also known as PDF. The free upgrade to Adobe Acrobat 5.0 or higher is recommended, especially if you have difficulty opening any of the documents below. Another method of obtaining guidance documents is through the Division of Drug Information.

[[Accessibility](#)]

CDER Guidance Documents 

Enter words or phrases, separated by commas
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- [FDA's Good Guidance Practices regulation of September 19, 2000](#). Optional Format: PDF.
- [Comprehensive List of Guidance Documents](#)  (updated 2/28/2006)
- [Guidance Agenda: Guidances CDER is Planning to Develop During Calendar Year 2006](#)  (03/01/2006)
- [New/Revised/Withdrawn List for 2006](#)  (updated 2/28/2006)
- [New/Revised/Withdrawn List for 2005](#)  (updated 1/4/2006)

Advertising

1. [Aerosol Steroid Product Safety Information in Prescription Drug Advertising and Promotional Labeling](#)  (Issued 12/1997, Posted 1/12/1998)
2. [Consumer-Directed Broadcast Advertisements](#) [[HTML](#)] or [[PDF](#)] (Issued 8/1999, Posted 8/6/1999)
[Questions and Answers](#) (Posted 8/6/1999)
3. [Industry-Supported Scientific and Educational Activities](#) [[HTML](#)] or [[PDF](#)] (Issued 12/3/1997, Posted 12/4/1997)

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[Biopharmaceutics](#)
[Biopharmaceutics \(Draft\)](#)
[CGMPs](#)
[CGMPs Draft](#)
[Chemistry](#)
[Chemistry\(Draft\)](#)
[Clinical/Antimicrobial](#)
[Clinical/Antimicrobial \(Draft\)](#)
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Advertising Draft

1. Accelerated Approval Products: Submission of Promotional Materials  (Posted 3/26/1999)
2. Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements [[HTML](#)] [[Word](#)] or [[PDF](#)] (Posted 2/4/2004)
 - o Labeling Example [[Word](#)] or [[PDF](#)]
 - o Labeling Example; Consumer-Friendly Version [[Word](#)] or [[PDF](#)]
3. Consumer-Directed Broadcast Advertising of Restricted Devices [[HTML](#)] or [[PDF](#)] (Issued 1/26/2004, Posted 2/4/2004)
4. "Help-Seeking" and Other Disease Awareness Communications by or on Behalf of Drug and Device Firms [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 1/26/2004, Posted 2/4/2004)
5. Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling  (Issued 1/1999, Posted 3/12/1999)
6. Promoting Medical Products in a Changing Healthcare Environment: I. Medical Product Promotion by Healthcare Organizations or Pharmacy Management Companies (PBMs)  (Issued 12/1997, Posted 1/5/1998)

Biopharmaceutics

1. Bioanalytical Method Validation [[HTML](#)] or [[PDF](#)] (Issued 5/2001, Posted 5/22/2001)
2. Bioavailability and Bioequivalence Studies for Orally Administered Drug Products - General Considerations [[Word](#)] or [[PDF](#)] (Issued 3/2003, Posted 3/19/2003)
3. Cholestyramine Powder in Vitro Bioequivalence (Interim Guidance) 
4. Clozapine Tablets: In Vivo Bioequivalence and In Vitro Dissolution Testing [[HTML](#)] or [[PDF](#)] or [[Word](#)] (Issued 6/17/2005, Posted 6/17/2005)
5. Corticosteroids, Dermatologic (topical) In Vivo  (Issued 6/2/1995, Posted 3/6/1998)
6. Dissolution Testing of Immediate Release Solid Oral Dosage Forms  or WordPerfect 6.x Version (Issued 8/1997, Posted 8/25/1997)
7. Extended Release Oral Dosage Forms: Development, Evaluation, and Application of In Vitro/In Vivo Correlations  (Issued 9/1997, Posted 9/26/1997)
8. Food-Effect Bioavailability and Fed Bioequivalence Studies [[Word](#)] or [[PDF](#)] (Issued 12/2002, Posted 1/30/2003)
9. Metaproterenol Sulfate and Albuterol Metered Dose Inhalers In Vitro  (Issued 6/27/1989, Posted 3/2/1998)
10. Potassium Chloride (slow-release tablets and capsules) In Vivo Bioequivalence and In Vitro Dissolution Testing  (Revised 6/6/1994, Posted 6/22/1998)
11. Statistical Approaches to Establishing Bioequivalence [[HTML](#)] or [[PDF](#)] (Issued 2/2001, Posted 2/1/2001)
12. Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System. Optional Format: PDF. (Issued 8/2000, Posted 8/31/2000)

Biopharmaceutics (Draft)

1. Bioavailability and Bioequivalence Studies for Nasal Aerosols and Nasal Sprays for Local Action [[Word](#)] or [[PDF](#)] (Posted 4/2/2003)
 - o Statistical Information from the June 1999 Draft Guidance and Statistical Information for In Vitro Bioequivalence Data  (Posted 4/11/2003)

2. Conjugated Estrogens, USP-LC-MS Method for Both Qualitative Chemical Characterization and Documentation of Qualitative Pharmaceutical Equivalence. Withdrawn per August 12, 2005, Federal Register notice.

CGMPs (Pharmaceutical CGMPs for the 21st Century)

1. Formal Dispute Resolution: Scientific and Technical Issues Related to Pharmaceutical CGMP [[HTML](#)] or [[PDF](#)] or [[Word](#)] (Issued 1/11/2006; Posted 1/11/2006)
2. Questions and Answers on Current Good Manufacturing Practices (cGMP) for Drugs (Posted 8/4/2004)
3. Part 11, Electronic Records; Electronic Signatures — Scope and Application [[HTML](#)] [[PDF](#)] [[Word](#)] (Posted 9/3/2003)
4. PAT — A Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance [[HTML](#)] [[PDF](#)] [[Word](#)] (posted 9/29/2004)
5. Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice [[HTML](#)] [[PDF](#)] [[Word](#)] Posted 9/29/2004

CGMPs (Pharmaceutical CGMPs for the 21st Century) -- Draft

1. Comparability Protocols - Protein Drug Products and Biological Products - Chemistry, Manufacturing, and Controls Information [[PDF](#)] [[Word](#)] (Posted 9/3/2003)
2. Current Good Manufacturing Practice for Combination Products [[HTML](#)] [[PDF](#)] [[Word](#)] (Posted 9/29/2004)
3. INDs--Approaches to Complying with CGMP's for Phase 1 Drugs [[HTML](#)] or [[PDF](#)] or [[Word](#)] (Issued 1/12/2006; Posted 1/12/2006)
4. Powder Blends and Finished Dosage Units — Stratified In-Process Dosage Unit Sampling and Assessment [[HTML](#)] [[PDF](#)] or [[Word](#)] (Issued 11/2003, Posted 11/6/2003)
 - o Revised Attachments [[Word](#)] or [[PDF](#)] (Issued 11/2003, Posted 11/21/2003)
5. Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations [[HTML](#)] [[PDF](#)] [[Word](#)] (Posted 9/29/2004)

Chemistry

1. BACPAC I: Intermediates in Drug Substance Synthesis; Bulk Actives Postapproval Changes: Chemistry, Manufacturing, and Controls Documentation [[HTML](#)] or [[PDF](#)] (Issued 2/2001, Posted 2/16/2001)
2. Botanical Drug Products [[HTML](#)] or [[PDF](#)] or [[Word](#)] (Issued 6/2004, Posted 6/9/2004)
3. Changes to an Approved Application for Specified Biotechnology and Specified Synthetic Biological Products  (Issued 7/1997, Posted 7/28/1997)
4. Changes to an Approved NDA or ANDA [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 4/2004, Posted 4/7/2004)
5. Changes to an Approved NDA or ANDA: Questions and Answers [[HTML](#)] or [[PDF](#)] (Issued 1/2001, Posted 1/22/2001)
6. Changes to an Approved NDA or ANDA; Specifications – Use of Enforcement Discretion for Compendial Changes [[HTML](#)] or [[PDF](#)] or [[Word](#)]. (Issued 11/19/2004, Posted 11/19/2004)
7. Container Closure Systems for Packaging Human Drugs and Biologics [[HTML](#)] or [[PDF](#)] (Issued 5/1999, Posted 7/6/1999)
 - o Container Closure Systems for Packaging Human Drugs and Biologics -- Questions

Chemistry (Draft)

1. Analytical Procedures and Methods Validation. Optional format: [PDF](#). (Issued 8/2000, Posted 8/30/2000)
2. Comparability Protocols -- Chemistry, Manufacturing, and Controls Information [[Word](#)] or [[Acrobat](#)] (Issued 2/2003, Posted 2/20/2003)
3. Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals  (Posted 9/11/2003)
4. Drug Product: Chemistry, Manufacturing, and Controls Information  (Issued 1/2003, Posted 1/28/2003)
5. Drug Substance: Chemistry, Manufacturing, and Controls Information [[Word](#)] or [[PDF](#)] (Issued 1/2004, Posted 1/6/2004)
6. Interpreting Sameness of Monoclonal Antibody Products Under the Orphan Drug Regulations [[HTML](#)] or [[PDF](#)] (7/24/1999)
7. Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI) Drug Products [[HTML](#)] or [[PDF](#)] or (Issued 11/13/1998, Posted 11/19/1998, HTML Posted 9/27/1999)
8. Liposome Drug Products: Chemistry, Manufacturing, and Controls; Human Pharmacokinetics and Bioavailability; and Labeling Documentation.  (Issued 7/2002, Posted 8/20/2002)
9. Stability Testing of Drug Substances and Drug Products  (Issued 6/5/1998, Posted 6/8/1998)
10. SUPAC-SS: Nonsterile Semisolid Dosage Forms Manufacturing Equipment Addendum  (Issued 12/1998, Posted 1/5/1999)

Clinical/Antimicrobial

1. Antiretroviral Drugs Using Plasma HIV RNA Measurements — Clinical Considerations for Accelerated and Traditional Approval [[Word](#)] or [[PDF](#)] (Issued 10/2002, Posted 10/31/2002)
2. Clinical Development and Labeling of Anti-Infective Drug Products [[HTML](#)] or [[PDF](#)] (Issued 10/1992, Posted 3/2/1998, Revised 2/12/2001)
3. Clinical Evaluation of Anti-Infective Drugs (Systemic)  (Issued 9/77, Posted 3/2/1998)

Clinical/Antimicrobial (Draft)

1. Acute Bacterial Exacerbation of Chronic Bronchitis — Developing Antimicrobial Drugs for Treatment  (Issued 7/22/1998, Posted 7/22/1998)
2. Acute Bacterial Meningitis — Developing Antimicrobial Drugs for Treatment  (Issued 7/22/1998, Posted 7/22/1998)
3. Acute Bacterial Sinusitis — Developing Antimicrobial Drugs for Treatment  (Issued 7/22/1998, Posted 7/22/1998)
4. Acute or Chronic Bacterial Prostatitis — Developing Antimicrobial Drugs for Treatment  (Issued 7/22/1998, Posted 7/22/1998)
5. Acute Otitis Media — Developing Antimicrobial Drugs for Treatment  (Issued 7/22/1998, Posted 7/22/1998)
6. Antiviral Drug Development -- Conducting Virology Studies and Submitting the Data to the Agency [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 5/24/2005, Posted 5/24/2005)
7. Bacterial Vaginosis — Developing Antimicrobial Drugs for Treatment  (Issued 7/22/1998, Posted 7/22/1998)

8. Catheter-Related Bloodstream Infections - Developing Antimicrobial Drugs for Treatment [HTML] or [PDF] (Issued 10/1999, Posted 10/18/1999)
9. Community-Acquired Pneumonia — Developing Antimicrobial Drugs for Treatment ✎ (Issued 7/22/1998, Posted 7/22/1998)
10. Complicated Urinary Tract Infections and Pyelonephritis — Developing Antimicrobial Drugs for Treatment (Issued 7/22/1998, Posted 7/22/1998) [HTML] or [PDF]
11. Developing Antimicrobial Drugs — General Considerations for Clinical Trials ✎ (Issued 7/22/1998, Posted 7/22/1998) [Main Document]
12. Empiric Therapy of Febrile Neutropenia — Developing Antimicrobial Drugs for Treatment ✎ (Issued 7/22/1998, Posted 7/22/1998)
13. Evaluating Clinical Studies Of Antimicrobials In The Division Of Anti-Infective Drug Products (2/18/1997) ✎
14. Inhalational Anthrax (Post Exposure) -- Developing Antimicrobial Drugs (Issued 3/15/2002, Posted 3/15/2002) [HTML] or [PDF]
15. Lyme Disease — Developing Antimicrobial Drugs for Treatment ✎ (Issued 7/22/1998, Posted 7/22/1998)
16. Nosocomial Pneumonia — Developing Antimicrobial Drugs for Treatment ✎ (Issued 7/22/1998, Posted 7/22/1998)
17. Role of HIV Drug Resistance Testing in Antiretroviral Drug Development [HTML] or [PDF] or [WORD] (Issued 11/26/04, Posted 11/26/04)
18. Secondary Bacterial Infections of Acute Bronchitis — Developing Antimicrobial Drugs for Treatment ✎ (Issued 7/22/1998, Posted 7/22/1998)
19. Streptococcal Pharyngitis and Tonsillitis — Developing Antimicrobial Drugs for Treatment ✎ (Issued 7/22/1998, Posted 7/22/1998)
20. Uncomplicated and Complicated Skin and Skin Structure Infections — Developing Antimicrobial Drugs for Treatment ✎ (Issued 7/22/1998, Posted 7/22/1998)
21. Uncomplicated Gonorrhea — Developing Antimicrobial Drugs for Treatment ✎ (Issued 7/22/1998, Posted 7/22/1998)
22. Uncomplicated Urinary Tract Infections — Developing Antimicrobial Drugs for Treatment ✎ (Issued 7/22/1998, Posted 7/22/1998)
23. Vaccinia Virus — Developing Drugs to Mitigate Complications from Smallpox Vaccination [HTML] or [Word] or [PDF] (Posted 3/8/2004)
24. Vulvovaginal Candidiasis — Developing Antimicrobial Drugs for Treatment ✎ (Issued 7/22/1998, Posted 7/22/1998)

Clinical/Medical

1. Acceptance of Foreign Clinical Studies [HTML] or [PDF] (Posted 3/12/2001)
2. Available Therapy [HTML] or [Word] or [PDF] (Posted 7/22/2004)
3. Calcium DTPA and Zinc DTPA Drug Products - Submitting a New Drug Application [HTML] or [Word] or [PDF] (Posted 8/13/2004)
4. Cancer Drug and Biological Products - Clinical Data in Marketing Applications [HTML] or [PDF] (Posted 10/11/2001)
5. Clinical Development Programs for Drugs, Devices, and Biological Products for the Treatment of Rheumatoid Arthritis (RA) (Issued 1/1999, Posted 2/16/1999) [HTML] or [PDF]
6. Clinical Development Programs for MDI and DPI Drug Products ✎ (Issued 9/19/1994, Posted 3/2/1998)
7. Clinical Evaluation of Analgesic Drugs (Withdrawn per August 5, 2003, Federal Register Notice)

- (Issued 9/77, Posted 3/2/1998)
36. Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment [HTML] or [Word] or [PDF] (Issued 3/24/2005, Posted 3/24/2005)
 37. Guidance for the Development of Vaginal Contraceptive Drugs (NDA) ✎ (Posted 3/2/1998)
 38. Information Sheet Guidance for Sponsors, Clinical Investigators, and IRBs: Waiver of IRB Requirements for Drug and Biological Product Studies [PDF] (Issued 1/2006)
 39. IND Exemptions for Studies of Lawfully Marketed Drug or Biological Products for the Treatment of Cancer [Word] or [PDF] (Revised 1/15/2004, Posted 1/15/2004)
 40. Internal Radioactive Contamination — Development of Decorporation Agents [HTML] or [PDF] (Issued 3/1/2006, Posted 3/1/2006)
 41. Integration of Dose-Counting Mechanisms into MDI Drug Products [Word] or [PDF] (Issued 3/2003, Posted 3/12/2003)
 42. Levothyroxine Sodium Tablets - In Vivo Pharmacokinetic and Bioavailability Studies and In Vitro Dissolution Testing [HTML] or [PDF] (Issued 2/2001, Posted 3/8/2001)
 43. Oncologic Drugs Advisory Committee Discussion on FDA Requirements for Approval of New Drugs for Treatment of Ovarian Cancer ✎ (Posted 3/2/1998)
 44. Oncologic Drugs Advisory Committee Discussion on FDA Requirements or Approval of New Drugs for Treatment of Colon and Rectal Cancer ✎ (Posted 3/2/1998)
 45. Premarketing Risk Assessment [HTML] or [Word] or [PDF] (Issued 3/24/2005; Posted 3/24/2005)
 46. Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products: Clarification of What to Report ✎ or WordPerfect 6.x version (Issued 8/27/1997, Posted 8/27/1997)
 47. Postmarketing Reporting of Adverse Drug Experiences ✎ (Issued 3/1992, Posted 3/2/1998)
 48. Preparation of Investigational New Drug Products (Human and Animal) ✎ (Issued 11/1992, Posted 3/2/1998)
 49. Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products ✎ (Issued 5/14/1998, Posted 5/14/1998)
 50. Prussian Blue Drug Products — Submitting a New Drug Application [Word] [PDF] (Issued 1/2003, Posted 2/4/2003)
 51. Study and Evaluation of Gender Differences in the Clinical Evaluation of Drugs ✎ (Issued 7/22/1993, Posted 3/2/1998)
 52. Study of Drugs Likely to be used in the Elderly ✎ (Issued 11/1989, Posted 3/2/1998)
 53. Submission of Abbreviated Reports and Synopses in Support of Marketing Applications [HTML] or [PDF] (Issued 8/1999, Posted 9/13/1999)
 54. The Use of Clinical Holds Following Clinical Investigator Misconduct [PDF] or [Word]

Clinical/Medical (Draft)

1. Acne Vulgaris: Developing Drugs for Treatment [HTML] or [Word] or [PDF] (Issued 9/16/2005, Posted 9/16/2005)
2. Allergic Rhinitis: Clinical Development Programs for Drug Products [HTML] or [PDF] (Issued 6/2000, Posted 6/20/2000)
3. Chronic Cutaneous Ulcer and Burn Wounds — Developing Products for Treatment [HTML] or [PDF] (Issued 6/2000, Posted 6/27/2000)
4. Clinical Development Programs for Drugs, Devices, and Biological Products Intended for the Treatment of Osteoarthritis [Word] or [PDF] (Issued 7/07/1999, Posted 7/14/1999)
5. Clinical Evaluation of Lipid-Altering Agents (Issued 10/1990, Posted 2/18/1998) ✎

6. Clinical Evaluation of Weight-Control Drugs (9/24/1996, Posted 2/18/1998) 
7. Clinical Trial Endpoints for the Approval of Cancer Drugs and Biologics [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 4/1/2005, Posted 4/1/2005)
8. Development of Parathyroid Hormone for the Prevention and Treatment of Osteoporosis [[HTML](#)] or [[PDF](#)] (Issued 5/2000, Posted 6/13/2000)
9. Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals [[HTML](#)] or [[PDF](#)] (Issued 9/6/2002)
10. Estrogen and Estrogen/Progestin Drug Products to Treat Vasomotor Symptoms and Vulvar and Vaginal Atrophy Symptoms — Recommendations for Clinical Evaluation [[Word](#)] or [[PDF](#)] (Issued 1/2003, Posted 1/30/2003)
11. Evaluation of the Effects of Orally Inhaled and Intranasal Corticosteroids on Growth in Children [[HTML](#)] or [[PDF](#)] (Posted 11/6/2001)
12. Exercise-Induced Bronchospasm (EIB) — Development of Drugs to Prevent EIB [[PDF](#)] (Issued 2/2002, Posted 2/19/2002)
13. Exocrine Pancreatic Insufficiency Drug Products – Submitting NDAs [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Posted 4/27/2004)
14. Female Sexual Dysfunction: Clinical Development of Drug Products for Treatment [[HTML](#)] or [[PDF](#)] (Issued 5/2000, Posted 5/18/2000)
15. Gingivitis: Development and Evaluation of Drugs for Treatment or Prevention [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued June 24, 2005, Posted June 27, 2005)
16. Guidance for Clinical Trial Sponsors On the Establishment and Operation of Clinical Trial Data Monitoring Committees [[HTML](#)] or [[PDF](#)] (Issued 12/01/2005, Posted 2/07/2006)
17. Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research (3/31/2000)
18. Inhalation Drug Products Packaged in Semipermeable Container Closure Systems [[PDF](#)] (Issued 7/2002, Posted 7/25/2002)
19. OTC Treatment of Herpes Labialis with Antiviral Agents [[HTML](#)] or [[PDF](#)] (Issued 3/8/2000, Posted 3/8/2000)
20. Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 2/2/2006, Posted 2/2/2006)
21. Pediatric Oncology Studies In Response to a Written Request [[HTML](#)] or [[PDF](#)] (Issued 6/2000, Posted 6/19/2000)
22. Preclinical and Clinical Evaluation of Agents Used in the Prevention or Treatment of Postmenopausal Osteoporosis (Issued 4/1994, Posted 2/18/1998) 
23. Recommendations for Complying with the Pediatric Rule (21 CFR 314.55(a) and 601.27 (a)) [[HTML](#)] or [[PDF](#)] (Posted 12/1/2000)
24. Systemic Lupus Erythematosus --Developing Drugs for Treatment [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 3/28/2005, Posted 3/28/2005)

Clinical Pharmacology

1. Drug Metabolism/Drug Interaction Studies in the Drug Development Process: Studies In Vitro  (Issued 4/1997, Posted 4/8/1997)
2. Exposure-Response Relationships — Study Design, Data Analysis, and Regulatory Applications [[Word](#)] or [[PDF](#)] (Posted 5/5/2003)
3. Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application*  (Issued 2/1987, Posted 3/2/1998)
4. In Vivo Drug Metabolism/Drug Interaction Studies - Study Design, Data Analysis, and Recommendations for Dosing and Labeling [[HTML](#)] or [[PDF](#)] (Issued 11/24/1999, Posted 11/24/1999)
5. Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data

- Analysis, and Impact on Dosing and Labeling [Word] or [PDF] (Posted 5/30/2003)
6. Pharmacokinetics in Patients with Impaired Renal Function  (Issued 5/14/1998, Posted 5/14/1998)
 7. Population Pharmacokinetics  (Issued 2/1999, Posted 2/10/1999)

Clinical Pharmacology (Draft)

1. Clinical Lactation Studies--Study Design, Data Analysis, and Recommendations for Labeling [HTML] or [PDF] or [Word] (Issued 2/7/05, Posted 2/8/05)
2. General Considerations for Pediatric Pharmacokinetic Studies for Drugs and Biological Products  (Issued 11/1998, Posted 11/12/1998)
3. Pharmacokinetics in Pregnancy — Study Design, Data Analysis, and Impact on Dosing and Labeling [HTML] or [Word] or [PDF] (Issued 10/29/2004, Posted 10/29/2004)

Combination Products (Drug/Device/Biologic)

- Draft and Final guidances can be found on the Office of Combination Products web site.

Compliance

1. A Review of FDA's Implementation of the Drug Export Amendments of 1986  (Issued 11/1989, Posted 3/2/1998)
2. Compressed Medical Gases (Issued 2/1989, Posted 3/10/1997)
3. Computerized Systems Used in Clinical Trials [HTML] - [Acrobat Version] (Issued 4/1999, Posted 5/11/1999)
4. General Principles of Process Validation
5. Good Laboratory Practice Regulations Questions and Answers  (Posted 3/2/1998)
6. Guidance for Hospitals, Nursing Homes, and Other Health Care Facilities - FDA Public Health Advisory [HTML] or [PDF] (Issued and Posted 4/5/2001)
7. Guideline for Validation of Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices  (Posted 3/2/1998)
8. Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron  (Issued 6/27/1997, Posted 6/27/1997)
9. Monitoring of Clinical Investigations  (Posted 3/2/1998)
10. Nuclear Pharmacy Guideline Criteria for Determining When to Register as a Drug Establishment  (Posted 3/2/1998)
11. Pharmacy Compounding -- Compliance Policy Guide  (Issued 5/2002, Posted 3/12/2004)
12. Possible Dioxin/PCB Contamination of Drug and Biological Products [HTML] or [PDF] (Issued 8/23/1999, Posted 8/23/1999)
13. Prescription Drug Marketing Act — Donation of Prescription Drug Samples to Free Clinics [HTML] or [PDF] (Issued 3/2006, Posted 3/13/2006)
14. Street Drug Alternatives [HTML] or [PDF] (Issued 3/2000, Posted 3/31/2000)

Compliance (Draft)

1. Bar Code Label Requirements -- Questions and Answers. [HTML] or [Word] or [PDF] (Issued 6/7/2005, Posted 6/7/2005)
2. Computerized Systems Used in Clinical Trials [HTML] [PDF] [Word] (Posted 9/29/2004)

3. Current Good Manufacturing Practice for Medical Gases [[Word](#)] or [[PDF](#)] (Posted 5/6/2003)
4. Expiration Dating of Unit-Dose Repackaged Drugs: Compliance Policy Guide [[HTML](#)] or [[Word](#)] or [[PDF](#)] (5/27/2005)
5. Guidance for IRBs, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research (21 CFR 50.24) Draft released for comment 3/30/2000 (5/12/2000)
6. Investigating Out of Specification (OOS) Test Results for Pharmaceutical Production (Issued 9/30/1998, Posted 9/30/1998)
7. Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients  (Issued 4/17/1998, Posted 4/17/1998)
8. Marketed Unapproved Drugs -- Compliance Policy Guide [[Word](#)] or [[PDF](#)] (Issued 10/15/2003, Posted 10/17/2003)
9. PET Drug Products - Current Good Manufacturing Practice (CGMP) [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 9/15/2005, Posted 9/15/2005)

Drug Safety

1. Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 2/2005, Posted 2/2005)

Drug Safety Draft

1. FDA's "Drug Watch" for Emerging Drug Safety Information [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 5/5/2005; Posted 5/5/2005)
 - o Questions and Answers (Qs & As) [[HTML](#)] or [[Word](#)] or [[PDF](#)]

Electronic Submissions

1. Part 11, Electronic Records; Electronic Signatures — Scope and Application [[HTML](#)] [[PDF](#)] [[Word](#)] (Posted 9/3/2003)
2. Providing Regulatory Submissions in Electronic Format — ANDAs [[HTML](#)] or [[PDF](#)] (Issued 6/2002, Posted 6/27/2002)
3. Providing Regulatory Submissions in Electronic Format — Content of Labeling [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 4/20/2005, Posted 4/20/2005)
4. Providing Regulatory Submissions in Electronic Format - Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications [[HTML](#)] or [[Word](#)] or [[PDF](#)]. To ensure you have the most recent versions of the specifications referenced in this document, check the appropriate center's guidance Web page. For CBER, this Web site is <http://www.fda.gov/cber/esub/esub.htm>. For CDER, this Web site is <http://www.fda.gov/cder/regulatory/ersr/ectd.htm>. (Issued 10/18/2005, Posted 10/18/2005)
5. Regulatory Submissions in Electronic Format; General Considerations  (Issued 1/1999, Posted 1/27/1999)
6. Regulatory Submissions in Electronic Format; New Drug Applications  (Issued 1/1999, Posted 1/27/1999)
7. SPL Standard for Content of Labeling Technical Qs & As [[HTML](#)] or [[PDF](#)] or [[Word](#)] (Issued 12/2005, Posted 12/8/2005)

Example of an Electronic New Drug Application Submission (Posted 2/17/1999).

Electronic Submissions Draft

1. Providing Regulatory Submissions in Electronic Format - Annual Reports for NDAs and ANDAs [[Word](#)] or [[PDF](#)] (Posted 8/27/2003)
2. Providing Regulatory Submissions in Electronic Format - General Considerations [[Word](#)] or [[PDF](#)] (Issued 10/2003, Posted 10/22/2003)
3. Providing Regulatory Submissions in Electronic Format - Postmarketing Expedited Safety Reports [[HTML](#)] or [[PDF](#)] (Issued 5/2001, Posted 5/3/2001)
4. Providing Regulatory Submissions in Electronic Format - Postmarketing Periodic Adverse Drug Experience Reports [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Posted 6/23/2003)
5. Providing Regulatory Submissions in Electronic Format - Prescription Drug Advertising and Promotional Labeling [[HTML](#)] or [[PDF](#)] (Issued 1/2001, Posted 1/30/2001)

Generics

1. 180-Day Exclusivity When Multiple ANDAs Are Submitted on the Same Day [[Word](#)] or [[PDF](#)] (Issued 7/2003, Posted 7/31/2003)
2. Alternate Source of the Active Pharmaceutical Ingredient in Pending ANDAs [[HTML](#)] or [[PDF](#)] (Posted 12/12/2000)
3. ANDA's: Impurities in Drug Substances [[HTML](#)] or [[PDF](#)] (Issued 11/1999, Posted 12/2/1999)
4. Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act [[HTML](#)] or [[PDF](#)] (Posted 3/27/2000)
5. Handling and Retention of BA and BE Testing Samples [[Word](#)] or [[PDF](#)] (5/25/2004)
6. Letter announcing that the OGD will now accept the ICH long-term storage conditions as well as the stability studies conducted in the past. ✎ (Posted 3/2/1998)
7. Letter describing efforts by the CDER and the ORA to clarify the responsibilities of CDER chemistry review scientists and ORA field investigators in the new and abbreviated drug approval process in order to reduce duplication or redundancy in the process. ✎ (Posted 3/2/1998)
8. Letter on incomplete Abbreviated Applications, Convictions Under GDEA, Multiple Supplements, Annual Reports for Bulk Antibiotics, Batch Size for Transdermal Drugs, Bioequivalence Protocols, Research, Deviations from OGD Policy. ✎ (Posted 3/2/1998)
9. Letter on the Provision of new information pertaining to new bioequivalence guidelines and refuse-to-file letters. ✎ (Posted 3/2/1998)
10. Letter on the provision of new procedures and policies affecting the generic drug review process. ✎ (Posted 3/2/1998)
11. Letter on the request for cooperation of regulated industry to improve the efficiency and effectiveness of the generic drug review process, by assuring the completeness and accuracy of required information and data submissions. ✎ (Posted 3/2/1998)
12. Letter on the response to 12/20/1984 letter from the Pharmaceutical Manufacturers Association about the Drug Price Competition and Patent Term Restoration Act. ✎ (Posted 3/2/1998)
13. Letter to all ANDA and AADA applicants about the Generic Drug Enforcement Act of 1992 (GDEA), and the Office of Generic Drugs intention to refuse-to-file incomplete submissions as required by the new law. ✎ (Posted 3/2/1998)
14. Letter to regulated industry notifying interested parties about important detailed information regarding labeling, scale-up, packaging, minor/major amendment criteria and

- bioequivalence requirements  (Posted 3/2/1998)
15. Major, Minor, and Telephone Amendments to Abbreviated New Drug Applications [PDF] (Issued 12/2001, Posted 12/20/2001)
 16. Potassium Chloride Modified-Release Tablets and Capsules: In Vivo Bioequivalence and In Vitro Dissolution Testing [HTML] or [PDF] or [Word] (Issued 10/25/2005; Posted 10/25/2005)
 17. Revising ANDA Labeling Following Revision of the RLD Labeling [HTML] or [PDF] (Issued 4/26/2000, 4/26/2000)
 18. Variations in Drug Products that May Be Included in a Single ANDA  (Issued 12/1998, Posted 1/26/1999)

Generics (Draft)

1. ANDAs: Impurities in Drug Products [HTML] or [Word] or [PDF] (Issued 8/26/2005, Posted 8/26/2005)
2. ANDAs: Impurities in Drug Substances [HTML] or [Word] or [PDF] (Issued 1/28/2005, Posted 1/28/2005)
3. ANDAs: Pharmaceutical Solid Polymorphism [HTML] or [Word] or [PDF]. (Issued 12/17/2004, Posted 12/17/2004)
4. Listed Drugs, 30-Month Stays, and Approval of ANDAs and 505(b)(2) Applications Under Hatch-Waxman, as Amended by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 -- Questions and Answers [HTML] or [Word] or [PDF]. (Issued 10/2004, Posted 11/3/2004)

Good Review Practices (GRPs)

1. Conducting a Clinical Safety Review of a New Product Application and Preparing a Report on the Review [Word] or [PDF] (Posted 2/18/2005)
2. Pharmacology/Toxicology Review Format [PDF] (Posted 5/9/2001) 

Good Review Practices (GRPs) (Draft)

Industry Letters

1. Continuation of a series of letters communicating interim and informal generic drug policy and guidance. Availability of Policy and Procedure Guides, and further operational changes to the generic drug review program  (Posted 3/2/1998)
2. Fifth of a series of letters providing informal notice about the Act, discussing the statutory mechanism by which ANDA applicants may make modifications in approved drugs where clinical data is required  (Posted 3/2/1998)
3. Fourth of a series of letters providing informal notice to all affected parties about policy developments and interpretations regarding the Act. Three year exclusivity provisions of Title I  (Posted 3/2/1998)
4. Implementation of the Drug Price Competition and Patent Term Restoration Act. Preliminary Guidance  (Posted 3/2/1998)
5. Implementation Plan USP injection nomenclature  (Posted 3/2/1998)
6. Seventh of a series of letters about the Act providing guidance on the "130-day exclusivity" provision of section 505(j)(4)(B)(iv) of the FD&C  (Posted 3/2/1998)
7. Sixth of a series of informal notice letters about the Act discussing 3- and 5-year exclusivity

1. Q1A(R2) Stability Testing of New Drug Substances and Products [[Word](#)] or [[PDF](#)] (Issued 11/2003, Posted 11/20/2003)
2. Q1B Photostability Testing of New Drug Substances and Products [[HTML](#)] or [[PDF](#)] (Issued 11/1996, Reposted 7/7/1998)
3. [Q1C Stability Testing for New Dosage Forms](#) ✎ (Issued 5/9/1997, Posted 3/19/1998)
4. Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products [[Word](#)] or [[PDF](#)] (Issued 1/2003, Posted 1/15/2003)
5. Q1E Evaluation of Stability Data [[HTML](#)] or [[PDF](#)] or [[Word](#)] (Issued 6/2004, Posted 6/7/2004)
6. Q1F Stability Data Package for Registration Applications in Climatic Zones III and IV, revision 1 [[HTML](#)] or [[Word](#)] or [[PDF](#)] (7/1/2004)
7. [Q2A Text on Validation of Analytical Procedures](#) ✎
8. [Q2B Validation of Analytical Procedures: Methodology](#) ✎ (Issued 5/19/1997, Posted 3/19/1997)
9. Q3A Impurities in New Drug Substances [[Word](#)] or [[PDF](#)] (Issued 2/10/2003, Posted 2/10/2003)
10. Q3B(R) Impurities in New Drug Products [[Word](#)] or [[PDF](#)] (Issued 11/2003, Posted 11/13/2003)
11. [Q3C Impurities: Residual Solvents or Adobe Acrobat version](#) ✎ (Issued 12/24/1997, Posted 12/30/1997)
Q3C Tables and List [[Word](#)] or [[PDF](#)] (Posted 11/12/2003)
Appendix 4, Appendix 5, and Appendix 6 (Appendices were issued with the Q3C draft guidance documents)
Maintenance Procedures for Updating (Posted 2/11/2002)
12. [Q5A Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin](#) (Posted 9/1998)
13. [Q5B Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products](#) ✎
14. [Q5C Quality of Biotechnological Products: Stability Testing of Biotechnological/Biological Products](#) ✎
15. [Q5D Quality of Biotechnological/Biological Products: Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products: Availability](#) ✎ (Issued 9/21/1998, Posted 9/21/1998)
16. Q5E Comparability of Biotechnological/Biological Products Subject to Changes in Their Manufacturing Process [[HTML](#)] or [[PDF](#)] or [[Word](#)] (Issued 6/2005, Posted 6/29/2005)
17. Q6A International Conference on Harmonisation; Guidance on Q6A Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances. [[Text](#)] or [[PDF](#)] (12/29/2000)
18. Q6B Specifications: Test Procedures and Acceptance Criteria for Biotechnological/Biological Products [[PDF](#)] (Issued 8/1999, Posted 12/14/2001)
19. Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients [[HTML](#)] or [[PDF](#)] (Issued 8/2001, Posted 9/24/2001)

International Conference on Harmonisation (Draft)

Efficacy

1. E2B(R) Clinical Safety Data Management: Data Elements for Transmission of Individual Case Safety Reports [[HTML](#)] or [[PDF](#)] or [[Word](#)] (Issued 9/30/2005, Posted 9/30/2005)
2. E2D Postapproval Safety Data Management: Definitions and Standards for Expedited

- Reporting [[PDF](#)] or [[Word](#)] (Posted 9/12/2003)
3. Principles for Clinical Evaluation of New Antihypertensive Drugs. Optional Format: [PDF](#). (Issued 8/2000, Posted 8/8/2000)

Joint Safety/Efficacy (Multidisciplinary) (Draft)

1. International Conference on Harmonisation; Draft Guidance on M5 Data Elements and Standards for Drug Dictionaries (Issued 9/2005, Posted 9/2/2005) [[PDF](#)] or [[Word](#)]
2. Submitting Marketing Applications According to the ICH/CTD Format: General Considerations (Issued 9/2001, Posted 9/5/2001) [[PDF](#)]

Quality

1. Q8 Pharmaceutical Development [[HTML](#)] or [[PDF](#)] or [[Word](#)] (Issued 2/7/2005, Posted 2/8/2005)
2. Q9 Quality Risk Management [[HTML](#)] or [[PDF](#)] or [[Word](#)] (Issued 8/5/2005, Posted 8/5/2005)

Safety

1. S8 Immunotoxicity Studies for Human Pharmaceuticals [[HTML](#)] or [[PDF](#)] or [[Word](#)] (Issued 2/7/05, Posted 2/8/05)

Investigational New Drug Applications

1. Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs 

Labeling

1. Adverse Reactions Section of Labeling for Human Prescription Drug and Biological Products — Content and Format [[HTML](#)] or [[PDF](#)] (Issued 1/18/2006; Posted 1/18/2006)
2. Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products — Content and Format [[HTML](#)] or [[PDF](#)] (Issued 1/18/2006; Posted 1/18/2006)
3. Content and Format for Geriatric Labeling [[HTML](#)] or [[PDF](#)] (Issued 10/2001, Posted 10/4/2001)

Labeling (Draft)

1. Labeling for Combined Oral Contraceptives [[PDF](#)] or [[Word](#)] (Issued 3/2/2004, Posted 3/4/2004)
2. Labeling for Human Prescription Drug and Biological Products — Implementing the New Content and Format Requirements [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 1/18/2006; Posted 1/18/2006)
3. Labeling Guidance for OTC Topical Drug Products for the Treatment of Vaginal Yeast Infections (Vulvovaginal Candidiasis)  (Issued 6/1998, Posted 7/20/1998)
4. Noncontraceptive Estrogen Drug Products for the Treatment of Vasomotor Symptoms and

Vulvar and Vaginal Atrophy Symptoms--Recommended Prescribing Information for Health Care Providers and Patient Labeling [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 11/15/2005, Posted 11/15/2005)

5. Referencing Discontinued Labeling for Listed Drugs in Abbreviated New Drug Applications [[HTML](#)] or [[PDF](#)] (Issued 10/2000, Posted 10/25/2000)
6. Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products — Content and Format [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 1/18/2006; Posted 1/18/2006)

Microbiology

1. Format and Content of the Microbiology Section of an Application* 

Modernization Act of 1997

1. Changes to an Approved NDA or ANDA [[Word](#)] or [[PDF](#)] (Issued 4/2004, Posted 4/7/2004)
2. Classifying Resubmissions in Response to Action Letters  (Issued 5/14/1998, Posted 5/14/1998)
3. Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act  or Word Version (Issued 11/1998, Posted 11/20/1998)
4. Fast Track Drug Development Programs - Designation, Development, and Application Review [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Posted 7/22/2004)
Appendix 2 ; Appendix 3  consisting of Mapp 6020.3 and SOPP 8405; and Appendix 4  [Appendices are scanned copies, which will be replaced by final versions] (Issued 11/17/1998, Posted 11/17/1998)
5. Formal Dispute Resolution: Appeals Above the Division Level [[HTML](#)] or [[PDF](#)] (Issued 2/2000, Posted 3/6/2000)
6. Formal Meetings With Sponsors and Applicants for PDUFA Products [[HTML](#)] or [[PDF](#)] (Issued 2/2000, Posted 3/6/2000)
7. Implementation of Section 120 of the Food and Drug Administration Modernization Act of 1997-Advisory Committees Wordperfect or Acrobat Version (Issued 10/1998, Posted 11/02/98)
8. Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997 - Elimination of Certain Labeling Requirements  (Issued 7/1998, Posted 7/20/98)
9. Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions [[HTML](#)] or [[PDF](#)] (Issued 3/2002, Posted 3/18/2002)
10. National Uniformity for Nonprescription Drugs - Ingredient Listing for OTC Drugs  (Issued 4/1998, Posted 5/5/1998)
11. Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products  (Issued 5/14/1998, Posted 5/14/1998)
12. Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act [[HTML](#)] or [[PDF](#)] (Issued 9/1999, Posted 10/4/1999)
 - o Frequently Asked Questions on Pediatric Exclusivity (505A), The Pediatric "Rule," and Their Interaction (Posted 7/27/1999)
13. Repeal of Section 507 of the Federal Food, Drug and Cosmetic Act  (Revised 5/1998, Posted 6/12/1998)
14. Standards for Prompt Review of Efficacy Supplements  (Issued 5/15/1998, Posted 5/15/1998)

15. Submission of Abbreviated Reports and Synopses in Support of Marketing Applications (Issued 8/1998, Posted 9/15/98) 
16. Submitting and Reviewing Complete Responses to Clinical Holds (Revised) [HTML] or [PDF] (Issued 10/2000, Posted 10/25/2000)
17. Women and Minorities Guidance Requirements  (Issued 7/20/1998, Posted 11/25/1998)

Modernization Act of 1997 (Draft)

1. Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions [Word] or [PDF] (Issued 1/2004, Posted 1/27/2004)
2. PET Drug Applications - Content and Format for NDAs and ANDAs [HTML] or [PDF] (Issued 3/7/2000, Posted 3/7/2000)
 - o Sample formats for chemistry, manufacturing, and controls sections [PDF] or [Word97]
 - o Sample formats for labeling [PDF] or [Word97]
 - o Sample formats for Form FDA 356h [PDF] or [Word97]
 - o Sample formats for user fee Form FDA 3397 [PDF] or [Word97]
3. Reports on the Status of Postmarketing Studies - Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 [HTML] or [PDF] (Posted 4/4/2001)

Over-the-Counter (OTC) Guidances

1. Enforcement Policy on Marketing OTC Combination Products (CPG 7132b.16)  (Posted 3/2/1998)
2. General Guidelines for OTC Combination Products  (Posted 3/2/1998)
3. Labeling OTC Human Drug Products Using a Column Format [HTML] or [PDF] (Issued 12/2000, Posted 12/18/2000)
4. Labeling OTC Human Drug Products Updating Labeling in RLDs and ANDAs [Word] or [PDF]

Example Drug Facts Labels

- o Acetaminophen 120 mg in a Suppository Dosage Form [PDF]
 - o Acetaminophen 325 mg in a Suppository Dosage Form [PDF]
 - o Acetaminophen 650 mg in a Suppository Dosage Form [PDF]
 - o Cimetidine 200 mg in a Tablet Dosage Form [PDF]
 - o Clemastine Fumerate 1.34 mg in a Tablet Dosage Form [PDF]
 - o Doxylamine Succinate 25 mg Tablet Dosage Form [PDF]
 - o Ibuprofen 200 mg in a Tablet/Capsule Dosage Form [PDF]
 - o Loperamide HCl in a Liquid Dosage Form [PDF]
 - o Loperamide HCl in a Tablet/Caplet Dosage Form [PDF]
 - o Miconazole Nitrate Vaginal Products [PDF]
 - o Minoxidil Topical Solution 2% for Men and Women [PDF]
 - o Minoxidil Topical Solution 5% for Men [PDF]
 - o Naproxen Sodium 220 mg in a Tablet/Caplet/Gelcap Dosage Form [PDF]
 - o Pseudoephedrine HCl Extended-Release Tablets 120 mg [PDF]
5. Upgrading Category III Antiperspirants to Category I (43 FR 46728-46731)  (Posted 3/2/1998)

Over-the-Counter (OTC) Draft

1. Labeling OTC Human Drug Products Questions and Answers [[HTML](#)] or [[PDF](#)] or [[Word](#)] (Issued 1/2005, Posted 1/12/05)
2. Labeling OTC Human Drug Products -Submitting Requests for Exemptions and Deferrals [[HTML](#)] or [[PDF](#)] (Issued 12/2000, Posted 12/18/2000)
3. Labeling OTC Human Drug Products (Small Entity Compliance Guide) [[Word](#)] [[PDF](#)] (Issued 12/2004, Posted 6/8/2005)
4. Labeling OTC Human Drug Products Updating Labeling in ANDAs [[HTML](#)] or [[PDF](#)] (2/21/2001)
 - o [Additional examples 1](#)  (3/19/2001)
 - o [Additional examples 2](#)  (3/26/2001)
 - o [Additional examples 3](#)  (3/26/2001)
5. Time and Extent Applications [[PDF](#)] or [[Word](#)] (Issued 2/2004, Posted 2/11/2004)

Pharmacology/Toxicology

1. Carcinogenicity Study Protocol Submissions [[HTML](#)] or [[PDF](#)] (Issued 5/22/2002)
2. Content and Format of INDs for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-Derived Products [[HTML](#)] or [[PDF](#)]
3. Developing Medical Imaging Drug and Biological Products
 - o Part 1: Conducting Safety Assessments [[Word](#)] or [[PDF](#)] (Issued 6/17/2004, Posted 6/17/2004)
4. Estimating the Maximum Safe Starting Dose in Initial Clinical Trials for Therapeutics in Adult Healthy Volunteers [[HTML](#)] or [[PDF](#)] or [[Word](#)] (Issued 7/21/2005, Posted 7/21/2005)
5. Exploratory IND Studies [[HTML](#)] or [[PDF](#)] or [[Word](#)] (Issued 1/12/2006; Posted 1/12/2006)
6. Format and Content of the Nonclinical Pharmacology/Toxicology Section of an Application*  (Posted 3/2/1998)
7. Immunotoxicology Evaluation of Investigational New Drugs [[Word](#)] or [[PDF](#)] (Issued 10/2002, Posted 10/31/2002)
8. Nonclinical Pharmacology/Toxicology Development of Topical Drugs Intended to Prevent the Transmission of Sexually Transmitted Diseases (STD) and/or for the Development of Drugs Intended to Act as Vaginal Contraceptives
9. Nonclinical Safety Evaluation of Drug or Biologic Combinations [[HTML](#)] or [[PDF](#)] (Issued 3/14/2006, Posted 3/14/2006)
10. Nonclinical Safety Evaluation of Pediatric Drug Products [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 2/14/2006, Posted 2/14/2006)
11. Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 05/18/2005, Posted 05/18/2005)
12. Photosafety Testing [[Word](#)] or [[PDF](#)] (Posted 5/7/2003)
13. Recommended Approaches to Integration of Genetic Toxicology Study Results [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 1/3/2006, Posted 1/3/2006)
14. Reference Guide for the Nonclinical Toxicity Studies of Antiviral Drugs Indicated for the Treatment of N/A Non-Life Threatening Disease Evaluation of Drug Toxicity Prior to Phase I Clinical Studies  (Posted 3/2/1998)
15. Single Dose Acute Toxicity Testing for Pharmaceuticals 

Pharmacology/Toxicology Draft

1. Integration of Study Results to Assess Concerns about Human Reproductive and

- Developmental Toxicities [[PDF](#)] (Issued 11/2001, Posted 11/9/2001)
- 2. Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals [[HTML](#)] or [[PDF](#)] or [[Word](#)] (Issued 6/17/2005; Posted 6/17/2005)
- 3. Safety Testing of Drug Metabolites [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 6/2005, Posted 6/3/2005)
- 4. Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals [[HTML](#)] or [[PDF](#)] (Issued 5/2001, Posted 5/7/2001)

Procedural

- 1. 180-Day Generic Drug Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act  (Issued 6/1998, Posted 6/22/1998)
- 2. Continuous Marketing Applications: Pilot 1 – Reviewable Units for Fast Track Products Under PDUFA [[Word](#)] or [[PDF](#)] (Posted 10/1/2003)
- 3. Continuous Marketing Applications: Pilot 2 – Scientific Feedback and Interactions During Development of Fast Track Products Under PDUFA [[Word](#)] or [[PDF](#)] (Posted 10/1/2003)
 - o Paperwork Reduction Act Burden Statement [[Word](#)] or [[PDF](#)] (Posted 7/27/2004)
- 4. Court Decisions, ANDA Approvals, and 180-Day Exclusivity Under the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act [[HTML](#)] or [[PDF](#)] (Posted 3/27/2000)
- 5. Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research Beginning on January 1, 2000 [[HTML](#)] or [[PDF](#)] (Issued 11/1999, Posted 11/29/1999)
- 6. Drug Products Containing Ensulizole, Hypromellose, Meradimate, Octinoxate, and Octisalate — Labeling Enforcement Policy [[Word](#)] or [[PDF](#)] (Posted 6/3/2003)
- 7. Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act  or Word Version (Issued 11/1998, Posted 11/20/1998)
- 8. Fast Track Drug Development Programs - Designation, Development, and Application Review [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Posted 1/12/2006)
Appendix 2 ; Appendix 3  consisting of Mapp 6020.3 and SOPP 8405; and Appendix 4  [Appendices are scanned copies, which will be replaced by final versions 11/18] (Issued 11/17/1998, Posted 11/17/1998)
- 9. FDA Export Certificates [[HTML](#)] or [[PDF](#)] (Issued 7/2004, Posted 7/13/2004)
- 10. Financial Disclosure by Clinical Investigators (3/27/2001)
- 11. Formal Dispute Resolution: Appeals Above the Division Level [[HTML](#)] or [[PDF](#)] (Issued 2/2000, Posted 3/6/2000)
- 12. Formal Meetings With Sponsors and Applicants for PDUFA Products [[HTML](#)] or [[PDF](#)] (Issued 2/2000, Posted 3/6/2000)
- 13. Good Review Management Principles and Practices for PDUFA Products [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 3/2005; Posted 3/30/2005)
- 14. Guidance for FDA Staff: The Leveraging Handbook; An Agency Resource for Effective Collaborations [[HTML](#)] or [[PDF](#)] (Revised 6/2003)
- 15. Implementation of Section 120 of the Food and Drug Administration Modernization Act of 1997-Advisory Committees [[Wordperfect](#)] or [[Acrobat Version](#)] (Issued 10/1998, Posted 11/02/98)
- 16. Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997 - Elimination of Certain Labeling Requirements  (Issued 7/1998, Posted 7/20/98)
- 17. Independent Consultants for Biotechnology Clinical Trial Protocols - [[HTML](#)] or [[PDF](#)] (Issued 8/18/2004, Posted 8/19/2004)
- 18. Information Program on Clinical Trials for Serious or Life-Threatening Diseases and

- Conditions [[HTML](#)] or [[PDF](#)] (Issued 3/2002, Posted 3/18/2002)
19. Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act [[HTML](#)] or [[PDF](#)] (Issued 11/2001)
 20. Levothyroxine Sodium Products Enforcement of August 14, 2001 Compliance Date and Submission of New Applications [[HTML](#)] or [[PDF](#)] (Issued 7/2001, Posted 7/12/2001)
 21. National Uniformity for Nonprescription Drugs - Ingredient Listing for OTC Drugs  (Issued 4/1998, Posted 5/5/1998)
 22. Pharmacogenomic Data Submissions [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 3/2005, Posted 3/22/2005)
 - o Examples of Voluntary Submissions or Submissions Required Under 21 CFR 312, 314, or 601 [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 3/2005, Posted 3/22/2005)
 23. Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies [[HTML](#)] or [[PDF](#)] (Issued 12/2001, Posted 12/10/2001)
 - o KI in Radiation Emergencies-Questions and Answers [[HTML](#)] or [[PDF](#)] (Issued 12/20/2002, Posted 12/23/2002)
 24. Potassium Iodide Tablets - Shelf Life Extension [[Word](#)] or [[PDF](#)] (Posted 3/8/2004)
 25. Reduction of Civil Money Penalties for Small Entities (Issued 3/20/2001)
 26. Qualifying for Pediatric Exclusivity Under Section 505A of the Federal Food, Drug, and Cosmetic Act [[HTML](#)] or [[PDF](#)] (Issued 9/1999, Posted 10/4/1999)
 27. Refusal to File  (Issued 7/12/1993, Posted 11/26/99)
 28. Repeal of Section 507 of the Federal Food, Drug and Cosmetic Act  (Revised 5/1998, Posted 6/12/1998)
 29. Reports on the Status of Postmarketing Study Commitments — Implementation of Section 130 of the Food and Drug Administration Modernization Act of 1997 [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 2/15/2006; Posted 2/15/2006)
 30. Special Protocol Assessment [[HTML](#)] or [[PDF](#)] (Issued 5/2002, Posted 5/16/2002)
 31. Standards for Prompt Review of Efficacy Supplements  (Issued 5/15/1998, Posted 5/15/1998)
 32. Submitting and Reviewing Complete Responses to Clinical Holds (Revised) [[HTML](#)] or [[PDF](#)] (Issued 10/2000, Posted 10/25/2000)

Procedural Draft

1. Applications Covered by Section 505(b)(2) [[HTML](#)] or [[PDF](#)] or [[Word](#)] (Issued 10/1999, Posted 12/7/1999)
2. Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by the Center for Drug Evaluation and Research, Beginning on January 1, 2000 [[HTML](#)] or [[PDF](#)] (Issued 12/1999, Posted 12/22/1999)
3. Disclosure of Conflicts of Interest for Special Government Employees Participating in FDA Product Specific Advisory Committees [[HTML](#)] or [[PDF](#)] (2/14/2002)
4. Emergency Use Authorization of Medical Products; Availability [[PDF](#)] (Issued 7/5/2005; Posted 7/5/2005)
5. Fixed Dose Combination and Co-Packaged Drug Products for Treatment of HIV [[HTML](#)] or [[PDF](#)] (5/17/2004)
6. Forms for Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution [[HTML](#)] or [[PDF](#)] (5/14/2001)
7. How to Comply with the Pediatric Research Equity Act [[PDF](#)] (Posted 9/7/2005)
8. Independent Consultants for Biotechnology Clinical Trial Protocols [[HTML](#)] or [[PDF](#)] (Posted 5/7/2003)
9. Information Program on Clinical Trials for Serious or Life-Threatening Diseases and

- Conditions [[Word](#)] or [[PDF](#)] (Issued 1/2004, Posted 1/27/2004)
10. PET Drug Applications - Content and Format for NDAs and ANDAs (Issued 3/7/2000, Posted 3/7/2000)
 - o Sample formats for chemistry, manufacturing, and controls sections 
 - o Sample formats for labeling 
 - o Sample formats for Form FDA 356h 
 - o Sample formats for user fee Form FDA 3397 
 11. Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines  (Issued 3/2001, Posted 3/9/2001)
 12. Submitting Debarment Certification Statements  (Issued 10/2/98, Posted 10/2/98)
 13. Submitting Marketing Applications According to the ICH/CTD Format: General Considerations [[PDF](#)] (Issued 9/2001, Posted 9/5/2001)
 14. The Use of Clinical Holds Following Clinical Investigator Misconduct  (Issued 4/2002, Posted 8/26/2002)
 15. Useful Written Consumer Medication Information (CMI) [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 5/25/2005, Posted 5/25/2005)
 16. Using a Centralized IRB Review Process in Multicenter Clinical Trials [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 3/25/2005, Posted 3/25/2005)

Small Entity Compliance Guides

1. Sterility Requirement for Aqueous-Based Drug Products for Oral Inhalation — Small Entity Compliance Guide [[PDF](#)] (Posted 11/7/2001)

Small Entity Compliance Guides (Draft)

1. Labeling OTC Human Drug Products (Small Entity Compliance Guide) [[Word](#)] [[PDF](#)] (Issued 12/2004, Posted 6/8/2005)

User Fees

1. Classifying Resubmissions in Response to Action Letters  (Issued 5/14/1998, Posted 5/14/1998)
2. Fees-Exceed-the-Costs Waivers Under the Prescription Drug User Fee Act [[HTML](#)] or [[PDF](#)] (Issued 6/1999, Posted 6/25/99)
3. Guidance for Industry and FDA Staff: Application User Fees for Combination Products.  (Issued 4/2005, Posted 5/3/2005)
4. Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act [[HTML](#)] or [[PDF](#)] (Issued 11/2001)
5. Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 12/30/2004, Posted 12/30/2004)

User Fees (Draft)

1. Attachment G -- Draft Interim Guidance Document for Waivers of and Reductions in User Fees  (7/16/1993)
2. User Fee Waivers for FDC and Co-Packaged HIV Drugs for PEPFAR [[HTML](#)] or [[Word](#)] or [[PDF](#)] (Issued 4/15/2005, Posted 4/15/2005)