

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N-0046]

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**Annual Comprehensive List of Guidance Documents at the Food and Drug Administration**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is publishing its annual comprehensive list of all guidance documents currently in use at the agency. This list is being published under 21 CFR 10.115(n)(2) of FDA's regulation on Good Guidance Practices (GGPs). This list is intended to inform the public of the existence and availability of all of our current guidance documents. It also provides information on guidance documents that have been added or withdrawn in the past year.

**DATES:** We welcome general comments on this list and on agency guidance documents at any time.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. We have provided information in the tables below on where to obtain a single copy of any of the guidance documents listed.

**FOR FURTHER INFORMATION CONTACT:** Carol A. Kimbrough, Office of Policy, Planning, and Legislation (HF-26), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3480.

**SUPPLEMENTARY INFORMATION:**

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## I. Background

We published our final rule on **GFPs** in **the Federal Register** of September 19, 2000 (65 FR 56468), and they became effective October 19, 2000. GFPs are intended to ensure involvement of the public in the development of **guidance** documents, and to enhance understanding of the availability, nature, and legal effect of such guidance. We committed in the GFPs to publishing annually a comprehensive list of guidance documents. This list updates a comprehensive list published July 21, 2000 (65 FR 45428).

The following comprehensive list identifies all final guidances that have been issued and are in use, and all draft guidances that have been distributed for comment and not for implementation. Any guidances that have been withdrawn this year are also listed. We have organized the documents by the issuing Center or Office within FDA, and we have identified the pertinent intended users or regulatory activities. The dates in the list refer to the date we issued the guidances or, where applicable, the last date we revised a document. Because each issuing Center or Office maintains its own database, there are slight variations in the way in which they provide information on the tables below.

The following most frequently used Internet sites for agency guidances are provided for future reference:

CBER: <http://www.fda.gov/cber/guidelines.htm>

CDER: <http://www.fda.gov/cder/guidance/index.htm>

CDRH: <http://www.fda.gov/cdrh/guidance.html>

CFSAN: <http://www.cfsan.fda.gov/~dms/guidance.html>

CVM: <http://www.fda.gov/cvm/guidance/published.htm#documents>

ORA: [http://www.fda.gov/ora/compliance\\_\\_ref](http://www.fda.gov/ora/compliance__ref)