Regulatory Information

Guidances

- FDA Guidance Documents: General and Cross-Cutting Topics
- Advisory Committee Guidance Documents
- Clinical Trials Guidance Documents
- Combination Products Guidance Documents
- Import and Export Guidance Documents
- International Conference on Harmonisation (ICH) Guidance Documents
- Veterinary International Conference on Harmonization (VICH) Guidance Documents

"Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices - Information Sheet

Guidance for Institutional Review Boards and Clinical Investigators

Good medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to their best knowledge and judgement. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. Use of a marketed product in this manner *when the intent is the "practice of medicine"* does not require the submission of an Investigational New Drug Application (IND), Investigational Device Exemption (IDE) or review by an Institutional Review Board (IRB). However, the institution at which the product will be used may, under its own authority, require IRB review or other institutional oversight.

Investigational Use of Marketed Drugs, Biologics and Medical Devices

The investigational use of approved, marketed products differs from the situation described above. "Investigational use" suggests the use of an approved product in the context of a clinical study protocol [see 21 CFR 312.3(b)]. When the principal intent of the investigational use of a test article is to develop information about the product's safety or efficacy, submission of an IND or IDE may be required. However, according to 21 CFR 312.2(b)(1), the clinical investigation of a marketed drug or biologic does not require submission of an IND if all six of the following conditions are met:

(i) it is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug;

(ii) it is not intended to support a significant change in the advertising for the product;

(iii) it does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product;

(iv) it is conducted in compliance with the requirements for IRB review and informed consent [21 CFR parts 56 and 50, respectively];

(v) it is conducted in compliance with the requirements concerning the promotion and sale of drugs [21 CFR 312.7]; and

(vi) it does not intend to invoke 21 CFR 50.24.

For additional information on whether or not an IND or IDE is required in a specific situation, contact:

For DRUG PRODUCTS, including BIOLOGICAL THERAPEUTICS, contact:

The relevant review division – contact information available at http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm075128.htm.

If the relevant review division is unknown contact:

Drug Information Branch
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue, Building 51, Room 2201
Silver Spring, Maryland 20993-0002
301-796-3400

For a BIOLOGICAL BLOOD or VACCINE product:
Office of Communication, Outreach and Development
Center for Biologic Evaluation and Research
Food and Drug Administration
1401 Rockville Pike
Rockville, Maryland 20852-1448
800-835-4709 or 301-827-1800

For a MEDICAL DEVICE product, contact:
Program Operations Staff
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue, Building 66, Room 1521
Silver Spring, Maryland 20993-0002
301-796-6560

Page Last Updated: 08/10/2011
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA(1-888-463-6332)
Email FDA

For Government | For Press

Combination Products
Advisory Committees
Science & Research
Regulatory Information
Safety
Emergency Preparedness
International Programs
News & Events
Training and Continuing Education
Inspections/Compliance
State & Local Officials
Consumers
Industry
Health Professionals
FDA Archive

U.S. Department of Health & Human Services