plan. FDA estimates that two recordkeepers per day (one recordkeeper for each shift) would be needed to conduct monitoring, corrective action, recordkeeping, and verification outlined in the risk control plan. The estimated duration of implementation for a risk control plan is 90 days, which is the minimum recommended time to achieve long-term behavior change.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR REGULATORS [1]

Types of Records	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Voluntary Food Safety Management System Evaluation (includes validation, verification, and completion of verification inspection checklist)	50,000	1	50,000	16	800,000
Total Annual Burden for Regulators					800,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

It is difficult to predict the number of State, local, and tribal regulatory jurisdictions that will use the Regulator's Manual. But, FDA anticipates that retail and foodservice establishments which voluntarily develop and implement a food safety management system based on the Operator's Manual will request their regulatory authorities to conduct an evaluation of their system. The estimates in table 2 of this document for the annual burden to State, local, and tribal regulators that follow the recommendations in the Regulator's Manual were calculated based on the usual time needed for one person to evaluate a voluntarily-implemented food safety management system and record the findings. The number of times an inspector may be asked by an operator to evaluate a voluntarily-implemented system is not expected to exceed once per year.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: December 11, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–30278 Filed 12–18–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0617]

Determination That RUBRAMIN PC (Cyanocobalamin) Injection and Ten Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the eleven drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to the drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Olivia Pritzlaff, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6308, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength andosage form as the ''listed drug,'' which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, a drug is withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved; (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved; and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for reasons of safety or effectiveness, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed. (As requested by the applicant, FDA withdrew approval of NDA 6–799 for RUBRAMIN PC (cyanocobalamin)

Injection in the **Federal Register** of November 7, 2007 (72 FR 62858).)

Application No.	Drug	Applicant
NDA 6–799	RUBRAMIN PC (cyanocobalamin) Injection, 1 milligram (mg)/milliliter (mL)	Bristol Myers Squibb Co., P.O. Box 4500, Princeton, NJ 08543–4500
NDA 10–060	FLORINEF (fludrocortisone acetate) Tablets, 0.1 mg	King Pharmaceuticals, Inc., 501 Fifth St., Bristol, TN 37620
NDA 11–613	IONAMIN (phentermine resin complex) Extended-Release Capsules, equivalent to (EQ) 15 mg and 30 mg base	UCB, Inc., 1950 Lake Park Dr., Smyrna, GA 30080
NDA 17–849	BRETHINE (terbutaline sulfate) Tablets, 2.5 mg and 5 mg	AAIPharma, LLC, 2320 Scientific Park Dr., Wilmington, NC 28405
NDA 17–970	NOLVADEX (tamoxifen citrate) Tablets, EQ 10 mg and 20 mg base	AstraZeneca Pharmaceuticals, 1800 Concord Pike, P.O. Box 8355, Wilmington, DE 19803–8355
NDA 19–058	TENORMIN (atenolol) Injection, 0.5 mg/mL	Do.
NDA 19–645	TORADOL (ketorolac tromethamine) Tablets, 10 mg	Hoffman-La Roche, Inc., 340 Kingsland St., Nutley, NJ 07110–1199
NDA 19–778	PRINZIDE (hydrochlorothiazide and lisinopril) Tablets, 25mg/20mg	Merck Research Laboratories, P.O. Box 1000, IG2C–50, North Wales, PA19454–1009
NDA 19–816	ORUVAIL (ketoprofen) Extended-Release Capsules, 100 mg, 150 mg, and 200 mg	Wyeth Pharmaceuticals, P.O. Box 8299, Philadelphia, PA 19101–8299
NDA 19–880	PARAPLATIN (carboplatin) for Injection, 50 mg/vial, 150 mg/vial, and 450 mg/vial	Bristol Myers Squibb Co.
NDA 50–582	DORYX (doxycycline hyclate) Delayed-Release Capsules, EQ 75 mg and 100 mg base	F.H. Faulding and Co., c/o Warner Chilcott, Inc., Rockaway 80 Corporate Center, 100 Enterprise Dr., suite 280, Rockaway, NJ 07866

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: December 11, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–30154 Filed 12–18–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0118]

Guidance for Industry on Diabetes Mellitus—Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Diabetes Mellitus—Evaluating Cardiovascular Risk in New Antidiabetic Therapies to Treat Type 2 Diabetes.'' This guidance makes recommendations about how to demonstrate that a new antidiabetic therapy to treat type 2 diabetes is not associated with an unacceptable increase in cardiovascular risk. We are issuing this guidance for immediate implementation to ensure that relevant issues related to minimizing cardiovascular risk are considered by all sponsors who have ongoing drug development programs for type 2 diabetes.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit