mental health issues, in particular, was found to be one of the weakest in the CFSRs. Areas of interest for research may examine CPS procedures for identifying and responding to children's mental health issues as well as the prevalence, type and severity of mental health problems among children identified in State child welfare systems. In addition, findings from the National Survey of Child and Adolescent Well-Being (NSCAW) show that high rates of mental health problems among parents, coupled with low rates of identification and referral, is a serious issue. CB is interested in research that examines mental health services to parents.

Program Evaluation of Priority Area Initiatives (or Evaluation of Programs Addressing Administration Priorities): The current Administration has focused funding in areas of healthy marriage promotion, fatherhood initiatives, community and faith-based organizations and youth development in ensuring the healthy development of children. CB is interested in research to evaluate programs employing these strategies to prevent child abuse and neglect. Research topics may include the evaluation of the effectiveness of these programs as well as the dissemination of promising practices.

Secondary Data Analysis: CB encourages the utilization of existing data sources particularly the use of service data through the National Child Abuse and Neglect Data System (NCANDS). CB is interested in secondary data analyses using NCANDS focusing on service utilization, recurrence and perpetrators.

Service utilization: While not all States provide complete service data to NCANDS, for those States that do provide complete service data, the following areas could be examined: The services that are most often provided to victims of maltreatment; differences in service patterns that exist between children who are first-time victims and children who are repeat victims; differences in service patterns that exist between child victims who remain in their homes and those who are removed; and the variations in service patterns within States according to county characteristics.

Recurrence: To date, recurrence has largely been examined for six-month periods using NCANDS data. The Office of the Assistant Secretary for Planning and Evaluation undertook a longitudinal analysis of NCANDS data examining repeated CPS involvement. Using a multiyear dataset of 1,396,998 children, this research examined the proportion of reported children who re-reported, the proportion of child victims who had a recurrence of maltreatment and the factors associated with these repeated events. The findings showed that re-reporting was relatively common—about one-third of children had at least one repeated report of maltreatment within a five-year period. For the most part, the same factors were related to both re-reporting of all reported children and recurrence among victims of maltreatment. Findings were also similar when analyses examined only the presence of a single subsequent event or the number and type of multiple subsequent events. Both re-reporting and recurrence occurred more frequently among younger children. Re-reporting and recurrence were more likely to occur in a short time following the initial maltreatment report, usually within a few months. Most children who experienced more than one re-report or re-victimization experienced these events within a short time after the initial event. Areas for further research might examine: Factors that are predictive of a second investigation; report sources that are the most likely to be associated with a second investigation; services that decrease subsequent investigation; and services that decrease subsequent victimization.

Perpetrators: CB continues to be interested in perpetrators, with the notion that understanding who this group is and what their characteristics are, can help to inform more effective intervention and prevention efforts. The Office of the Assistant Secretary for Planning and Evaluation undertook an analysis of NCANDS data examining some of these questions. The analysis focused on male perpetrators of child maltreatment and identifies clear subgroups of male perpetrators. The findings suggest that interventions of all types may need to be more highly differentiated for these different groups. Follow-up of interest includes research to gain a clearer picture of how the various categories of perpetrators fit within households to provide insights into the service and recidivism outcomes.

C. Field Initiated Research on Child Abuse and Neglect

The generation of new knowledge for understanding critical issues in child abuse and neglect improves prevention, identification, assessment and treatment. Research areas to be addressed may be those that will expand the current knowledge base, build on prior research, contribute to practice enhancements, inform policy, improve science and provide insights into new approaches to the assessment, prevention, intervention and treatment of child maltreatment (i.e., physical abuse, sexual abuse, emotional maltreatment or neglect) on any of the topics listed in (A) Legislative Topics, (B) Other Topics, above, or any other child maltreatment topic.

In addition to the topics cited above, practitioners and researchers are encouraged to propose other relevant subjects for research topics in child abuse and neglect.

Joan E. Ohl,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. E6–1480 Filed 2–2–06; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005P–0023]

Determination That TEQUIN (Gatifloxacin) Injection, 10 Milligrams per Milliliter (200 Milligrams), Was 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 TEQUIN (gatifloxacin) injection, 10 milligrams (mg) per milliliter (mL) (200 mg), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for gatifloxacin injection, 10 mg/mL (200 mg).

FOR FURTHER INFORMATION CONTACT: Elaine Tseng, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the 1984 amendments) (Pub. L. 98–417), 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 and dosage form as the ''listed drug,'' which is typically 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 (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, drugs are 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 21 CFR 314.161(a)(1), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), is the subject of approved NDA 21–062 held by Bristol-Myers Squibb. TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), is an antibiotic used to treat adults with lung, sinus, or urinary tract infections.

FDA approved the NDA for TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg) and 10 mg/mL (400 mg), on December 17, 1999. On January 27, 2003, FDA received revised product labeling relating to several approved supplements for TEQUIN (gatifloxacin). This revised labeling deleted references to TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), indicating that this product was no longer being marketed. Therefore, it was moved from the prescription drug product list to the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Apotex Corp., submitted a citizen petition dated January 13, 2005 (Docket No. 2005P–0023/CP1), under 21 CFR 10.30, requesting that the agency determine whether TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), was withdrawn from sale for reasons of safety or effectiveness. After considering the citizen petition and reviewing agency records, FDA has determined that TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), approved under NDA 21–062, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), was withdrawn from sale as a result of safety or effectiveness concerns. FDA's independent evaluation of relevant literature and data has not uncovered anything that would indicate that this product was withdrawn for reasons of safety or effectiveness. Accordingly, the agency will continue to list TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), in the ''Discontinued Drug Product List'' section of the Orange Book. ANDAs that refer to TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), may be approved by the agency.

Dated: January 27, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1475 Filed 2–2–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004E–0389]

Determination of Regulatory Review Period for Purposes of Patent Extension; SURPASS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for SURPASS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that animal drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6681.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For animal drug products, the testing phase begins on the earlier date when either a major environmental effects test was initiated for the drug or when an exemption under section 512(j) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(j)) became effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the animal drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for an animal drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(4)(B).

FDA recently approved for marketing the animal drug product SURPASS (diclofenac sodium). SURPASS is indicated for the control of pain and inflammation associated with osteoarthritis in tarsal, carpal, metacarpophalangeal, metatarsophalangeal, and proximal interphalangeal (hock, knee, fetlock, and pastern) joints in horses. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for SURPASS (U.S. Patent No. 4,937,078) from Mezei Associates, Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated April 8, 2005, FDA advised the Patent and Trademark Office that this animal drug product had undergone a regulatory review period and that the approval of SURPASS represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.