

October 27, 2000, and related determinations.

**EFFECTIVE DATE:** November 27, 2000.

**FOR FURTHER INFORMATION CONTACT:** Madge Dale, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3772.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster for the State of Arizona is hereby amended to include the following area among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of October 27, 2000:

Yavapai County for Individual Assistance.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 83.537, Community Disaster Loans; 83.538, Cora Brown Fund Program; 83.539, Crisis Counseling; 83.540, Disaster Legal Services Program; 83.541, Disaster Unemployment Assistance (DUA); 83.542, Fire Suppression Assistance; 83.543, Individual and Family Grant (IFG) Program; 83.544, Public Assistance Grants; 83.545, Disaster Housing Program; 83.548, Hazard Mitigation Grant Program)

**Lacy E. Suiter,**

*Executive Associate Director, Response and Recovery Directorate.*

[FR Doc. 00-30707 Filed 12-01-00; 8:45 am]

**BILLING CODE 6718-02-P**

## FEDERAL RESERVE SYSTEM

### Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than December 18, 2000.

A. Federal Reserve Bank of Dallas (W. Arthur Tribble, Vice President) 2200 North Pearl Street, Dallas, Texas 75201-2272:

1. *Carl W. Ellis*, Perryton, Texas; to acquire additional voting shares of FirstPerryton Bancorp, Inc., Perryton, Texas, and FirstPerryton Delaware, Inc., Dover, Delaware, and thereby indirectly acquire additional voting shares of First Bank Southwest, N.A., Amarillo, Texas.

Board of Governors of the Federal Reserve System, November 28, 2000.

**Robert deV. Frierson,**

*Associate Secretary of the Board.*

[FR Doc. 00-30758 Filed 12-1-00; 8:45 am]

**BILLING CODE 6210-01-P**

## FEDERAL TRADE COMMISSION

### Charges for Certain Disclosures

**AGENCY:** Federal Trade Commission.

**ACTION:** Notice regarding charges for certain disclosures.

**SUMMARY:** The Federal Trade Commission announces that the current \$8.50 ceiling on allowable charges under Section 612(a) of the Fair Credit Reporting Act ("FCRA") will remain unchanged for 2001. Under 1996 amendments to the FCRA, the Federal Trade Commission is required to increase the \$8.00 amount referred to in paragraph (1)(A)(i) of Section 612(a) on January 1 of each year, based proportionally on changes in the Consumer Price Index ("CPI"), with fractional changes rounded to the nearest fifty cents. The CPI increased 7.75 percent between September 1997, the date the FCRA amendments took effect, and September 2000. This increase in the CPI and the requirement that any increase be rounded to the nearest fifty cents results in no change in the current maximum allowable charge of \$8.50.

**EFFECTIVE DATE:** January 1, 2001.

**ADDRESSES:** Federal Trade Commission, Washington, DC 20580.

**FOR FURTHER INFORMATION CONTACT:**

Keith B. Anderson, Bureau of Economics, Federal Trade Commission, Washington, DC 20580, 202-326-3428.

**SUPPLEMENTARY INFORMATION:** Section 612(a)(1)(A) of the Fair Credit Reporting Act, as amended in 1996, states that, where a consumer reporting agency is permitted to impose a reasonable charge on a consumer for making a disclosure to the consumer pursuant to Section 609, the charge shall not exceed \$8 and shall be indicated to the consumer before making the disclosure. Section 612(a)(2) goes on to state that the Federal Trade Commission ("the Commission") shall increase the \$8.00 maximum amount on January 1 of each year, based proportionally on changes in

the Consumer Price Index, with fractional changes rounded to the nearest fifty cents.

The Commission considers the \$8 amount referred to in paragraph (1)(A)(i) of Section 612(a) to be the baseline for the effective ceiling on reasonable charges dating from the effective date of the amended FCRA, *i.e.*, September 30, 1997. Each year the Commission calculates the proportional increase in the Consumer Price Index (using the most general CPI, which is for all urban consumers, all items) from September 1997 to September of the current year. The Commission then determines what modification, if any, from the original base of \$8 should be made effective on January 1 of the subsequent year, given the requirement that fractional changes be rounded to the nearest fifty cents.

Between September 1997 and September 2000, the Consumer Price Index for all urban consumers and all items increased by 7.75 percent—from an index value of 161.2 in September 1997 to a value of 173.7 in September 2000. An increase of 7.75 percent in the \$8.00 base figure would lead to a new figure of \$8.62. However, because the statute directs that the resulting figure be rounded to the nearest \$0.50, the allowable charge should be \$8.50.

The Commission therefore determines that the allowable charge for the year 2001 will remain unchanged at \$8.50.

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

[FR Doc. 00-30811 Filed 12-1-00; 8:45 am]

**BILLING CODE 6750-01-M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 00N-1639]

### SangStat Medical Corp.; Withdrawal of Approval of an Abbreviated New Drug Application; Cyclosporine

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing approval of an abbreviated new drug application (ANDA) held by SangStat Medical Corp., 6300 Dumbarton Circle, Fremont, CA 94555 (Sangstat). The ANDA is for SangCya Oral Solution (Cyclosporine Oral Solution, USP) Modified, which was the subject of a class II recall announced on July 10, 2000. SangStat has agreed in writing to

permit FDA to withdraw approval of the application and has waived its opportunity for a hearing.

**EFFECTIVE DATES:** January 3, 2001.

**FOR FURTHER INFORMATION CONTACT:**

David T. Read, Center for Drug Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

**SUPPLEMENTARY INFORMATION:** On July 10, 2000, SangCya Oral Solution (Cyclosporine Oral Solution, USP) Modified, 100 milligrams per milliliter, was the subject of a class II recall under 21 CFR part 7 (Ref. 1). The recall of the drug product, marketed under ANDA 64-195, arose from data recently submitted by SangStat to the agency regarding the bioavailability of the product in healthy subjects when administered with apple juice. Following the recall, SangStat notified the agency in writing on July 21, 2000, that the company had decided to permanently withdraw the product from the market. On August 4, 2000, SangStat requested in writing that the agency withdraw approval of ANDA 64-195. Subsequently, SangStat provided the agency with a full and complete waiver of the company's right to a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(e)) to allow the agency to complete the withdrawal of approval under 21 CFR 314.150(d).

Therefore, under section 505(e) of the act and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.82), approval of ANDA 64-195, and all amendments and supplements thereto, is hereby withdrawn, effective January 3, 2001. The effective date of the withdrawal of approval is intended to allow patients the opportunity to complete their transition to another cyclosporine drug product (see Ref. 1). Thereafter, distribution of the product in interstate commerce without an approved application is illegal and subject to regulatory action. Also, on the basis of the circumstances described above that led to the recall of the product and its subsequent removal from the market, the agency will remove the product from the agency's list of drug products with effective approvals, published under the title "Approved Drug Products with Therapeutic Equivalence Evaluations." This document serves as notice of the removal of the product covered by ANDA 64-195, SangCya Oral Solution, from the list of approved drug products.

**Reference**

The following reference has been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The document may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. The document is available on the Internet at: <http://www/fda.gov/bbs/topics/ANSWERS/ANS01025.html>.

1. FDA Talk Paper dated July 10, 2000.

Dated: November 21, 2000.

**Janet Woodcock,**

*Director, Center for Drug Evaluation and Research.*

[FR Doc. 00-30773 Filed 12-1-00; 8:45 am]

**BILLING CODE: 3510-22-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. 00D-1601]**

**Guidance for Industry and for FDA Employees on Import Alert #66-66; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Import Alert #66-66, Detention Without Physical Examination of API's That Appear To Be Misbranded Under 502(f)(1) Because They Do Not Meet the Requirements for the Labeling Exemptions in 21 CFR 201.122." This document provides guidance for industry and FDA employees on FDA's interpretation of the Federal Food, Drug, and Cosmetic Act (the act) and the labeling exemptions in title 21 of the Code of Federal Regulations regarding bulk chemicals that can be used as active pharmaceutical ingredients (API's) and may be destined for pharmaceutical processors formulating finished drug products. The document includes FDA's guidance to industry and FDA district offices for detention without physical examination of API's from certain manufacturers.

**DATES:** Submit written comments on the guidance to the Dockets Management Branch (address below) by February 2, 2001. After February 2, 2001, submit written comments to the contact person listed below.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled "Import Alert #66-66,

Detention Without Physical Examination of API's That Appear To Be Misbranded Under 502(f)(1) Because They Do Not Meet the Requirements for the Labeling Exemptions in 21 CFR 201.122" to the Division of Import Operations and Policy (HFC-170), Office of Regulatory Affairs, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your requests. You may fax your request to 301-594-0413. Submit written comments on this guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

**FOR FURTHER INFORMATION CONTACT:**

Thaddeus J. Poplawski, Division of Import Operations and Policy (HFC-170), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-6553.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

A large volume of bulk chemicals that can be used as API's in human medicines are being offered for entry into the United States. In order to be used as a pharmaceutical, an API is required to be included in an FDA approved new drug application (NDA), abbreviated new drug application (ANDA), or investigational new drug application (IND).

Imported API's labeled for further manufacturing and processing or labeled as chemical substances are frequently destined for pharmaceutical processors that formulate finished drug products under approved NDA's. These drug substances, consigned to individuals or processors who formulate and distribute human drugs, may be misbranded under section 502(f)(1) of the act (21 U.S.C. 352(f)(1)).

Sponsors of IND's frequently import from foreign countries either the dosage form or the API for use in laboratory research or clinical trials.

Some persons importing API's have found that they could obtain entry of these articles if they simply supply an NDA or IND number at the point of entry. FDA is advising its district offices that they should be alert to the possibility that: (1) The NDA or IND number provided does not cover the source of the particular API or (2) the persons importing the API have no authorization to refer to the particular NDA or IND number.