Enforcement) 101 Market Street, San Francisco, California 94105–1579:

1. *Castle Creek Capital Partners IV, LP, Castle Creek Advisors IV, LLC, Castle Creek Capital IV, LLC, John T. Pietrzak, Pietrzak Advisory Corp., John M. Eggemeyer, JME Advisory Corp., William J. Ruh, Ruh Advisory Corp., Mark G. Merlo, Legions IV Advisory Corp., Joseph Mikesell Thomas, and Mikesell Advisory Corp., all of Rancho Santa Fe, California as a group acting in concert,* to acquire control of Intermountain Community Bancorp, and thereby indirectly acquire control of Panhandle State Bank, both of Sandpoint, Idaho.

Board of Governors of the Federal Reserve System, June 1, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–13883 Filed 6–3–11; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than July 1, 2011.

A. Federal Reserve Bank of Richmond (Adam M. Drimer, Assistant Vice President), 701 East Byrd Street, Richmond, Virginia 23261–4528:

1. ASB Bancorp, Inc., Asheville, North Carolina, to become a bank holding company upon the conversion of Asheville Savings Bank, S.S.B., Asheville, North Carolina, from a mutual to stock form of ownership.

Board of Governors of the Federal Reserve System, June 1, 2011.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 2011–13882 Filed 6–3–11; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0279]

Agency Information Collection Activities: Proposed Collection; Reports and Records Under Prescription Drug Marketing Act of 1987

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting and recordkeeping requirements contained in the regulations implementing the Prescription Drug Marketing Act of 1987 (PDMA).

DATES: Submit either electronic or written comments on the collection of information by August 5, 2011.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Prescription Drug Marketing Act of 1987; Administrative Procedures, Policies, and Requirements—21 CFR Part 203 (OMB Control Number 0910–0435)—Extension

FDA is requesting OMB approval under the PRA (44 U.S.C. 3501–3520) for the reporting and recordkeeping requirements contained in the regulations implementing the Prescription Drug Marketing Act of 1987 (PDMA) (Public Law 100–293). PDMA was intended to ensure that drug products purchased by consumers are safe and effective and to avoid an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs are sold.

PDMA was enacted by Congress because there were insufficient safeguards in the drug distribution system to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs, and that a wholesale drug diversion submarket had developed that prevented effective control over the true sources of drugs.

Congress found that large amounts of drugs had been reimported into the United States as U.S. goods returned causing a health and safety risk to U.S. consumers because the drugs may become subpotent or adulterated during foreign handling and shipping. Congress also found that a ready market for prescription drug reimports had been the catalyst for a continuing series of frauds against U.S. manufacturers and had provided the cover for the importation of foreign counterfeit drugs.

Congress also determined that the system of providing drug samples to physicians through manufacturers' representatives had resulted in the sale to consumers of misbranded, expired, and adulterated pharmaceuticals.

The bulk resale of below-wholesale priced prescription drugs by health care entities for ultimate sale at retail also helped to fuel the diversion market and was an unfair form of competition to wholesalers and retailers who had to pay otherwise prevailing market prices.

FDA is requesting OMB approval for the following reporting and recordkeeping requirements:

TABLE 1—REPORTING REQUIREMENTS

21 CFR 203.11	Applications for reimportation to provide emergency medical care.
21 CFR 203.30(a)(1) and (b)	Drug sample requests (drug samples distributed by mail or common carrier).
21 CFR 203.30(a)(3), (a)(4), and (c)	Drug sample receipts (receipts for drug samples distributed by mail or common carrier).
21 CFR 203.31(a)(1) and (b)	Drug sample requests (drug samples distributed by means other than the mail or a common carrier).
21 CFR 203.31(a)(3), (a)(4), and (c)	Drug sample receipts (drug samples distributed by means other than the mail or a common carrier).
21 CFR 203.37(a)	Investigation of falsification of drug sample records.
21 CFR 203.37(b)	Investigation of a significant loss or known theft of drug samples.
21 CFR 203.37(c)	Notification that a representative has been convicted of certain offenses involving drug samples.
21 CFR 203.37(d)	Notification of the individual responsible for responding to a request for information about drug samples.
21 CFR 203.39(g)	Preparation by a charitable institution of a reconciliation report for donated drug samples.

TABLE 2—RECORDKEEPING REQUIREMENTS

21 CFR 203.23(a) and (b)	Credit memo for returned drugs.
21 CFR 203.23(c)	Documentation of proper storage, handling, and shipping conditions for returned drugs.
21 CFR 203.30(a)(2) and 203.31(a)(2)	Verification that a practitioner requesting a drug sample is licensed or authorized by the appropriate State authority to prescribe the product.
21 CFR 203.31(d)(1) and (d)(2)	Contents of the inventory record and reconciliation report required for drug samples distributed by representatives.
21 CFR 203.31(d)(4)	Investigation of apparent discrepancies and significant losses revealed through the reconciliation report.
21 CFR 203.31(e)	Lists of manufacturers' and distributors' representatives.
21 CFR 203.34	Written policies and procedures describing administrative systems.
21 CFR 203.37(a)	Report of investigation of falsification of drug sample records.
21 CFR 203.37(b)	Report of investigation of significant loss or known theft of drug samples.
21 CFR 203.38(b)	Records of drug sample distribution identifying lot or control numbers of samples distributed. (The information collection in 21 CFR 203.38(b) is already approved under OMB Control Number 0910–0139).
21 CFR 203.39(d)	Records of drug samples destroyed or returned by a charitable institution.
21 CFR 203.39(e)	Record of drug samples donated to a charitable institution.
21 CFR 203.39(f)	Records of donation and distribution or other disposition of donated drug samples.
21 CFR 203.39(g)	Inventory and reconciliation of drug samples donated to charitable institutions.
21 CFR 203.50(a)	Drug origin statement.
21 CFR 203.50(b)	Retention of drug origin statement for 3 years.
21 CFR 203.50(d)	List of authorized distributors of record.

The reporting and recordkeeping requirements are intended to help achieve the following goals: (1) To ban the reimportation of prescription drugs produced in the United States, except when reimported by the manufacturer or under FDA authorization for emergency medical care; (2) to ban the sale, purchase, or trade, or the offer to sell, purchase, or trade, of any prescription drug sample; (3) to limit the distribution of drug samples to practitioners licensed or authorized to prescribe such drugs or to pharmacies of hospitals or other health care entities at the request of a licensed or authorized practitioner; (4) to require licensed or authorized practitioners to request prescription drug samples in writing; (5) to mandate storage, handling, and recordkeeping requirements for prescription drug samples; (6) to prohibit, with certain exceptions, the sale, purchase, or trade of, or the offer to sell, purchase, or trade, prescription drugs that were purchased by hospitals or other health care entities, or which were donated or supplied at a reduced price to a charitable organization; (7) to require unauthorized wholesale distributors to provide, prior to the wholesale distribution of a prescription drug to another wholesale distributor or

retail pharmacy, a statement identifying each prior sale, purchase, or trade of the drug.

FDA estimates the burden of this collection of information as follows:

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response (in hours)[2]	Total hours
203.11	1	1	1	30/60	.50
203.30(a)(1) and (b)	61,961	12	743,532	4/60	44,612
203.30(a)(3), (a)(4), and (c)	61,961	12	743,532	4/60	44,612
203.31(a)(1) and (b)	232,355	135	31,367,925	2/60	1,254,717
203.31(a)(3), (a)(4), and (c)	232,355	135	31,367,925	2/60	941,038
203.37(a)	50	4	200	15/60	50
203.37(b)	50	40	2,000	15/60	500
203.37(c)	1	1	1	1	1
203.37(d)	50	1	50	5/60	4
203.39(g)	1	1	1	1	1
Total					2,285,535.50

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping (in hours)[2]	Total hours
203.23(a) and (b)	31,676	5	158,380	15/60	39,595
203.23(c)	31,676	5	158,380	5/60	12,670
203.30(a)(2) and 203.31(a)(2)	2,208	100	220,800	30/60	110,400
203.31(d)(1) and (d)(2)	2,208	1	2,208	40	88,320
203.31(d)(4)	442	1	442	24	10,608
203.31(e)	2,208	1	2,208	1	2,208
203.34	90	1	90	40	3,600
203.37(a)	50	4	200	6	1,200
203.37(b)	50	40	2,000	6	1,200
203.39(d)	65	1	65	1	65
203.39(e)	3,221	1	3,221	30/60	1,610
203.39(f)	3,221	1	3,221	8	25,768
203.39(g)	3,221	1	3,221	8	25,768
203.50(a)	125	100	12,500	10/60	2,125
203.50(b)	125	100	12,500	30/60	6,250
203.50(d)	691	1	691	2	1,382
Total					332,769

[1] There are capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

Dated: May 24, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–13442 Filed 6–3–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0375]

Collaboration in Regulatory Science and Capacity To Advance Global Access to Safe Vaccines and Biologicals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces its intention to accept and consider a single source application for award of a cooperative agreement to the World Health Organization (WHO) in support of collaboration in regulatory science and capacity of National Regulatory Authorities (NRAs) to advance global access to safe and effective vaccines and other biologicals that meet international standards. The goal of FDA's Center for Biologics Evaluation and Research (FDA/CBER) is to enhance technical collaboration and cooperation between FDA, WHO, and its Member States.

DATES: Important dates are as follows:

1. The application due date is July 8, 2011.

2. The anticipated start date is August 15, 2011.