

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0845]

Bracco Diagnostics et al.; Withdrawal of Approval of 52 New Drug Applications and 77 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** on July 19, 2013. The document announced the withdrawal of approval of 52 new drug applications (NDAs) and 77 abbreviated new drug applications (ANDAs) from multiple applicants, withdrawn as of August 19, 2013. The document erroneously included the withdrawal of ANDA 075328 for Pemoline tablets, 18.75 milligrams (mg), 37.5 mg, and 75 mg, held by Vintage Pharmaceuticals, 120 Vintage Dr., Huntsville, AL 35811. This notice corrects that error.

FOR FURTHER INFORMATION CONTACT:

Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993-0002, 301-796-3137, Kimberly.Lehrfeld@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of Friday, July 19, 2013 (78 FR 43210), appearing on page 43213 in FR Doc. 2013-17324, the following correction is made:

On page 43213, in the table, the entry for ANDA 075328 is removed.

In a separate notice published in this issue of the **Federal Register**, FDA is withdrawing the approval of ANDA 075328 under 21 CFR 314.150(d).

Dated: May 31, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Purchased/Referred Care Delivery Area Redesignation for the Hoh Indian Tribe in the State of Washington

AGENCY: Indian Health Service, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Indian Health Service (IHS) has decided to expand the geographic boundaries of the Purchased/Referred Care Delivery Area (PRCDA) for the Hoh Indian Tribe in the State of Washington to include the county of Clallam in the State of Washington. The final PRCDA for the Hoh Indian Tribe is now the Washington counties of Jefferson and Clallam. The sole purpose of this expansion is to authorize additional Hoh Indian Tribe members and beneficiaries to receive Purchased/Referred Care (PRC) services.

DATES: This expansion is effective as of the publication date of this notice.

ADDRESSES: This notice can be found at <https://www.federalregister.gov>. Written requests for information should be delivered to: CAPT John Rael, Director, Office of Resource Access and Partnerships, Indian Health Service, 5600 Fishers Lane, Mail Stop 10E85C, Rockville, MD 20857, or by phone at (301) 443-0609 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The IHS provides services under regulations in effect as of September 15, 1987, and republished at 42 CFR part 136, subparts A-C. Subpart C defines a Contract Health Service Delivery Area (CHSDA), now referred to as a PRCDA, as the geographic area within which PRC will be made available by the IHS to members of an identified Indian community who reside in the PRCDA. Residence within a PRCDA by a person who is within the scope of the Indian health program, as set forth in 42 CFR 136.12, creates no legal entitlement to PRC but only potential eligibility for services. Services needed, but not available at an IHS/Tribal facility, are provided under the PRC program depending on the availability of funds, the person's relative medical priority, and the actual availability and accessibility of alternate resources in accordance with the regulations.

The regulations at 42 CFR part 136, subpart C provide that, unless otherwise designated, a PRCDA shall consist of a county which includes all or part of a reservation and any county or counties which have a common boundary with the reservation. 42 CFR 136.22(a)(6). The regulations also provide that after consultation with the Tribal governing body or bodies on those reservations included within the PRCDA, the Secretary may from time to time redesignate areas within the United States for inclusion in or exclusion from a PRCDA. 42 CFR 136.22(b). The

regulations require that certain criteria must be considered before any redesignation is made. The criteria are as follows:

(1) The number of Indians residing in the area proposed to be so included or excluded;

(2) Whether the Tribal governing body has determined that Indians residing in the area near the reservation are socially and economically affiliated with the Tribe;

(3) The geographic proximity to the reservation of the area whose inclusion or exclusion is being considered; and

(4) The level of funding which would be available for the provision of PRC.

Additionally, the regulations require that any redesignation of a PRCDA must be made in accordance with the procedures of the Administrative Procedure Act (5 U.S.C. 553). 42 CFR 136.22(c). In compliance with this requirement, the IHS published a proposed notice of redesignation and requested public comments on January 18, 2023 (88 FR 2940). In response, the IHS received one comment and that comment expressed support of the proposed expansion.

Through a letter from the Hoh Indian Tribe, dated July 28, 2021, the Tribe expressed its support for the expansion, described the geographic proximity of Clallam County to the Tribe's reservation, and explained why many of its members need to live in the town nearest to the reservation, which is in Clallam County. In support of this expansion, the IHS adopts the following findings:

1. By expanding the PRCDA to include Clallam County, the Hoh Indian Tribe's eligible population will be increased by an estimated 41 Tribal members residing in Clallam County. This expansion will increase the Hoh Indian Tribe's total PRC-eligible population to 73.

2. The IHS is construing the letter from the Tribe, dated July 28, 2021, to mean that the Tribal members within the expanded PRCDA are socially and economically affiliated with the Hoh Indian Tribe.

3. Clallam County in the State of Washington is "on or near" the reservation, as described by the Tribe in its correspondence dated July 28, 2021, and as it maintains a common boundary with the current PRCDA consisting of Jefferson County in the State of Washington.

4. The Portland Area IHS administers the PRC program for the Hoh Indian Tribe and will use its existing Federal allocation for PRC funds to provide services to the expanded population. No additional financial resources will be