



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-0419]

Pan American Laboratories, LLC, et al.; Withdrawal of Approval of Three New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of three new drug applications (NDAs) from multiple holders of those NDAs. The basis for the withdrawal is that these NDA holders have repeatedly failed to file required annual reports for those NDAs.

DATES: Approval is withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

FOR FURTHER INFORMATION CONTACT: Kimberly S. 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.

SUPPLEMENTARY INFORMATION: The holder of an approved application to market a new drug for human use is required to submit annual reports to FDA concerning its approved application in accordance with § 314.81 (21 CFR 314.81).

In the *Federal Register* of November 18, 2019 (84 FR 63661), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of these NDAs because the holders of those NDAs had repeatedly failed to submit the required annual reports for those NDAs. The holders of the NDAs identified in table 1 did not respond to the

NOOH. Failure to file a written notice of participation and request for hearing as required by § 314.200 (21 CFR 314.200) constitutes an election by those holders of the NDAs not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of their NDAs and a waiver of any contentions concerning the legal status of the drug products. Therefore, FDA is withdrawing approval of the three applications listed in table 1 of this document. FDA notes that the NOOH also proposed to withdraw approval of NDA 018663, but FDA has decided not to pursue withdrawal of approval of this NDA at this time.

Table 1.--Approved NDAs for Which Required Reports Have Not Been Submitted

| Application No. | Drug | NDA Holder |
|-----------------|--|---|
| NDA 014217 | Maolate (chlorphenesin carbamate) Tablet, 400 milligrams (mg) | Pan American Laboratories, LLC, 4099 Highway 190, Covington, LA 70433 |
| NDA 020530 | Iontocaine (epinephrine and lidocaine hydrochloride (HCl)) Topical Solution, 0.01 mg/milliliter; 2% | Iomed, Inc., 2441 South 3850 West, Suite A, Salt Lake City, UT 84120-9941 |
| NDA 021504 | LidoSite Topical System: LidoSite Patch (lidocaine HCl and epinephrine topical iontophoretic patch) 10%/0.1% and LidoSite Controller | Vyteris, Inc., 13-01 Pollitt Dr., Fair Lawn, NJ 07410 |

FDA finds that the holders of the NDAs listed in table 1 have repeatedly failed to submit reports required by § 314.81. In addition, under § 314.200, FDA finds that the holders of the NDAs have waived any contentions concerning the legal status of the drug products. Therefore, under these findings, approval of the NDAs listed in table 1 and all amendments and supplements thereto are hereby withdrawn as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].¹

¹Although it was not a factor in FDA's determination, we note that all three drugs covered by these NDAs are in discontinued marketing status.

Dated: March 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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