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OTC Decisions August-October: More Providers Enter Diclofenac, Lansoprazole, Loratadine Markets

by Malcolm Spicer

CDER's August-September OTC application approvals are highlighted by Arbor Pharmaceuticals' ivermectin 0.5% lice treatment. Orange Book changes also include four firms' approvals for labeling to market generic equivalents of Voltaren Arthritis Relief launched as an OTC switch since earlier in 2020.

Editor's note: HBW Insight's ongoing feature provides information on decisions during August-October by the US Food and Drug Administration on new drug applications, including ANDAs, for nonprescription drugs and on supplemental NDAs about label and package changes for approved OTC products.

The past three months offered relatively little in the way of additional OTC drug products approved for sales in the US until the final week of the period with Arbor Pharmaceuticals LLC receiving approval to introduce ivermectin 0.5% as a nonprescription lice treatment.

In other OTC application decisions by the Food and Drug Administration's Center for Drug Evaluation and Research from August through October, Tenshi Kaizen Private Ltd. received approval for the first generic equivalent of the Claritin Reditab loratadine 5-mg orally disintegrating tablets while Rubicon Research Pvt. Ltd. became the sixth firm with approval for a copy of the 10-mg Clarin Reditab formulation.

Yichang Humanwell Pharmaceutical Co. Ltd., meanwhile, is the latest manufacturer with approval to provide 200-mg ibuprofen oral analgesic in the US.

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ARBOR PHARMACEUTICALS HAS AN APPROVED LABEL FOR NONPRESCRIPTION SKLICE, ABOVE, BUT THE OTC SWITCH APPROVED IN OCTOBER IS NOT AVAILABLE FOR SALE YET.

CDER's Orange Book updates of the three months also include four firms' approvals for label additions for their generic equivalents of Voltaren Arthritis Relief (diclofenac 0.1 gel), which GlaxoSmithKline PLC launched as an OTC switch since earlier in 2020.

Sklice Makes Five

Arbor Pharmaceuticals received *CDER's approval* on 29 October for Sklice gel in a full OTC switch of ivermectin 0.5% for the topical treatment of head lice infestations in patients six months of age and older. The Atlanta-based firm had marketed the formulation Rx under the brand since

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2012 and will continue using the brand for an OTC single-use lotion. (Also see "*In Latest US OTC Switch, Ivermectin 0.5% Lice Treatment Becomes Fully Nonprescription*" - HBW Insight, 27 Oct, 2020.)

With Arbor Pharmaceuticals' product the only Rx ivermectin 0.5% that has been approved for lice treatment available in the US, the same formulation no longer will be available by prescription, though higher concentrations of the ingredient, including formulations for pets, will remain Rx only.

The firm touts Sklice as the No. 1 prescribed "brand for head lice" based on its own data. Atlanta-based Arbor Pharmaceuticals' product is the fifth OTC switch CDER has approved in 2020, starting in February with Voltaren Arthritis Pain and 0.2% once-daily and 0.1% twice-daily formulations of olopatadine drops Alcon Laboratories Inc. markets under the Pataday brand. (Also see "*US OTC Switch Drought Ends: FDA Approves GSK Arthritis Gel, Alcon Allergy Eye Drops*" - HBW Insight, 17 Feb, 2020.)

Olopatadine became a full switch in July with the FDA's approval of Alcon's sNDA for an OTC product indicated for ocular allergies, or allergic conjunctivitis, with 0.7% concentration of the ingredient and marketed as Once Daily Relief Extra Strength. (Also see "*With Pataday Extra Strength, Alcon Eyes Consumers Looking For OTC 24-Hour Eye Allergy Remedy*" - HBW Insight, 13 Jul, 2020.)

WALGREENS DICLOFENIAC 0.1% GEL IS ONE OF SEVERAL PRIVATE LABEL OR STORE BRAND PRODUCTS MADE BY ENCUBE ETHICALS WHICH BECAME AVAILABLE IN THE US AFTER ITS ANDA FOR LABEL AND INSERT CHANGES WAS APPROVED IN AUGUST.

Pataday also was on CDER's radar on September. It approved Alcon Labs' sNDA changes to labeling, containers and cartons for the 0.2% and 0.1% formulations; the approval letters and images of the changes were not included in the Orange Book entry.

More Claritin Reditab Generics

Rubicon Research on 10 September received CDER's approval of its ANDA for 10-mg loratadine in an orally disintegrating formulation like Bayer AG's Claritin Reditab product, which also is marketed as a hives treatment. Mumbai, India-based Rubicon is the sixth firm with approval to provide in the US an ingredient recognized as a generic equivalent of Claritin Reditab.

Tenshi Kaizen, of Bengaluru, India, on 18 September received approval to provide 5-mg orally disintegrating loradatine in the US. The approval is the first generic competition for Bayer's 5-mg Claritin Reditab formulation.

Bayer, meanwhile, received approval on 7 August for an sNDA on labeling for an 80-count package of cool mint flavor Children's Claritin in chewable 5- and 10-mg loratadine formulations.

Chinese firm Yichang Humanwell Pharmaceutical is the 17th manufacturer to receive CDER's approval to provide in the US 200-mg ibuprofen that follow on the Advil brand marketed by GlaxoSmithKline plc. The center approved the firm's ANDA on 19 October.

Sofgen Pharmaceuticals LLC, of Dania Beach, FL, on 6 August received approval for an sNDA for changes to labeling, containers and cartons for its 200-mg ibuprofen formulated as a free acid and potassium salt as GSK uses in Advil Liqui-Gels.

Rx Diclofenac Gels Move To OTC

GSK, like other drug firms, was marketing diclofenac 0.1% gel external analgesic in Rx drugs before it received the FDA's approval to market the formulation OTC Voltaren Arthritis Relief. The FDA approval for the UK pharma's switch didn't come with three-year marketing exclusivity because a clinical trial wasn't required in the sNDA. (Also see "*US OTC Switch Drought Ends: FDA Approves GSK Arthritis Gel, Alcon Allergy Eye Drops*" - HBW Insight, 17 Feb, 2020.)

Perrigo Co. plc, received approval for its ANDA for an OTC diclofenac 0.1% gel in April, before GSK launched sales of Voltaren Arthritis Relief. (Also see "*Perrigo Has Approval For Copy Of OTC Voltaren Arthritis Relief Before GSK Launches The Brand*" - HBW Insight, 6 Apr, 2020.)

CDER's OTC decisions over the past three months indicate three other firms have label or package inserts approved for their generic equivalents of Voltaren Arthritis Relief. However, unlike Perrigo, the other three firms don't have an entry for approval for OTC sales of their diclofenac 0.1% gels before they received CDER's approval of label or package inserts for nonprescription products.

Mylan N.V.'s OTC diclofenac 0.1% gel ANDA for labeling or inserts was approved on 6 August. Mylan, which is merging with Pfizer Inc.'s Upjohn business for mature Rx brand and off-patent products, had a prescription formulation approved in May 2019. (Also see "*Divided FTC Okays Mylan-Upjohn Merger But Election Outcome Could Impede Future Deals*" - Pink Sheet, 30 Oct, 2020.)

Indian firm Encube Ethicals Ltd.'s labeling and inserts ANDA for an OTC generic of Voltaren Arthritis Relief was approved on 11 August. The Indian firm's Rx of the product was approved in January, shortly before CDER approved GSK's OTC switch of the formulation.

Amneal Pharmaceuticals LLC's Rx diclofenac 0.1 gel was approved in 2016; the Bridgewater, NJ-based business of Swiss firm Amneal Pharmaceuticals Company GmbH received CDER's approval for its ANDA for labeling and inserts for a generic equivalent of Voltaren Arthritis Relieaf on 13 August.

Dublin-based Perrigo's ANDA for labeling and inserts ANDA for its diclofenac 0.1% gel was approved on 23 October. Prior to receiving CDER's approval for the OTC product in April, it acquired an Rx formulation that had been approved for Capstone Development Solutions in 2016.

More Lansoprazole PPI Providers

Perrigo also was one of three firms to receive CDER's approval during the three months for labeling and inserts for 15-mg lansoprazole in delayed-release tablets, generic equivalents of Prevacid 24HR, which Perrigo also markets after acquiring the proton pump inhibitor brand from GSK in September 2019. (Also see "*Perrigo Feeds OTC Brand Play With Prevacid As GSK Thins Consumer Lineup*" - HBW Insight, 5 Sep, 2019.)

The approval letter and images of the labeling and inserts for Perrigo's and the other firm's lansoprazole ANDAs were not included in the Orange Book entries. The labeling and inserts changes likely follow the *latest changes approved* for Prevacid 24HR labeling, in April 2019. An sNDA GSK submitted before selling the brand was approved to add to labels the statement, "Ask a doctor or pharmacist before use if you are taking a prescription drug. Acid reducers may interact with certain prescription drugs."

The other OTC lansoprazole 15-mg lansoprazole delayed-release tablet providers with approvals

for labeling and insert changes were Dr Reddy's Laboratories Ltd. on 7 October and Lannett Co. Inc. on 8 October.

Dr Reddy's also continued expanding its US nicotine replacement therapy footprint during the past three months. The Indian firm on 4 August became the fourth manufacturer approved to provide in the US generics of GSK's Nicorette (nicotine polacrilex) 2- and 4-mg lozenges.