The New England Chapter of the PDA

Workshop on Development

and

Commercialization of Combination Products

Commercialization of an Iontophoretic Drug Delivery System

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The Drug Device Combination Product

Background

- The LidoSite™ product
  - a local anesthetic for topical use
  - a drug/device combination
  - primary mode of action is pharmaceutical
  - jurisdiction assigned to CDER's Division of Anesthetic, Critical Care, and Addictive Drug Products
  - a collaboration with CDRH's Division of General, Restorative and Neurological Devices

Regulatory Plan

- Submissions
  - an “umbrella” IND for the development of the Iontophoretic patch
  - a New Drug Application for the patch
  - a 510(k) for the controller
- Ombudsman
  - Requested help to facilitate communication between CDER and CDRH

Commercialization

- Quality System
- Scale Up
- Validation
- Marketing and Distribution
- Reporting
- Labeling
- Registrations and Listings

Quality System

- Drug cGMP vs QSR
  - Controller was designed and developed under QSR Design Controls
  - Patch developed with the pharmaceutical development report approach
  - Quality System was a hybrid system to accommodate both regulations
    (21CFR210, 211 and 820)

Scale Up

- Patch Manufacturing
  - Solution manufacturing (2)
    - Anode (drug) and cathode
  - Patch fabrication
  - Patch pouching
  - Packaging/Labeling
- Device Manufacturing
  - Outsourced to a contract manufacturer

Validation

- Validation (IQ/OQ/PQ)
  - Facility (HVAC, water, etc.)
  - Equipment
  - Process
  - Computer
  - Analytical and Physical Test Methods
  - Documentation/training

Marketing and Distribution

- Patch and Controller sold separately
  - Patch - single use disposable
  - Controller – multiple use
- Licensed to B. Braun
  - Product Samples
  - Demonstration product
- Advertised as a system

Reporting

- Post marketing Requirements
  - Drug
    - Field Alert Report
    - Periodic Safety Reports
      - 15 day “alert reports” MedWatch FDA Form 3500A
      - quarterly reports
    - Annual Report
  - Device
    - 5 day Reports
    - Baseline Report
    - Annual Report

Labeling

- Product
  - Carton and container labels
  - Package Insert/Instructions for Use
    - PI/IFU covered both the patch and controller
    - Negotiated the “indications for use”
- Other
  - Advertising and Promotional Material
    - Submitted to DDMAC

Registrations and Listings

- Drug Product Listing-Form FDA 2657
- Drug Establishment/Labeler Code-Form FDA 2656
- Medical Device Listing-Form FDA 2892
- Device Establishment Registration-Form FDA 2891 - (initial)