Section 2 – 510(k) Summary

APR - 4 2008

2.1 Submission Applicant & Correspondent

Applicant: Coria Laboratories, Ltd.
3909 Hulen St.
Fort Worth, TX 76107

Contact: Amy Campbell
Phone: (817) 302-3901

2.2 Name of Device

Proprietary Name: Tetrix™ Cream
Common Name: Dressing, wound and burn, hydrogen w/drug and/or biologic
Classification Name: Dressing, wound and burn, hydrogen w/drug and/or biologic

2.3 Devices to Which New Device is Substantially Equivalent

Sinclair Wound	K024367 marketed as AtopiClair™ and Skin Emulsion Nonsteroidal Cream
Mimyx™ Cream	K041342

2.4 Device Description

Tetrix™ Cream is a non-sterile cream formulation intended for prescription use only.

Clinical studies provided evidence that Tetrix™ Cream prevents nickel salts, neomycin and a mixture of fragrances from making contact with the skin. Please see clinical studies section.

2.5 Intended Use of the Device

Tetrix™ Cream is indicated to manage and relieve the burning and itching experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and irritant contact dermatitis. Tetrix™ Cream helps to relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

2.6 Summary of Technological Characteristics of the Device Compared to the Predicate Devices

All products referenced are non sterile emulsion/gel types that are applied topically to manage the symptoms of various types of dermatoses.

2.7 Tests and Conclusions

Functional and performance testing has been conducted to assess the safety and effectiveness of Tetrix™ Cream and the results are satisfactory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 4 2008

Coria Laboratories, Ltd.
% Healthpoint, Ltd.
Ms. Amy Campbell
3909 Hulen Street
Fort Worth, Texas 76107

Re: K071483
Trade/Device Name: Tetrix Cream
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 3, 2008
Received: April 3, 2008

Dear Ms. Campbell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071483

Device Name: Tetrix™ Cream

Indications For Use:

Tetrix™ Cream is indicated to manage and relieve the burning and itching experienced with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis and irritant contact dermatitis. Tetrix™ Cream helps to relieve dry, waxy skin by maintaining a moist wound and skin environment, which is beneficial to the healing process.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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