K052289

DEC 14 2005

PREMARKET NOTIFICATION
510(k) SUMMARY

1. *Submitter's Name:* Schering-Plough HealthCare Products, Inc.
   Address: 3 Connell Drive, Berkeley Heights, NJ 07922
   Telephone Number: (908) 679-1305
   Contact Person: John O'Mullane, PhD
   Date Prepared: August 15, 2005

2. *Device Name:*
   Proprietary Name: Dr. Scholl's® Dual Action Freeze Away™ Wart Remover
   Usual Name: OTC Wart Removal System
   Classification Name: Unit, Cryosurgical, Accessories (21 CFR 878.4350, Product Code GEH)

3. *Devices to Which Substantial Equivalence is Claimed:*
   Modification to Dr. Scholl's® Freeze Away™ Wart Remover, by Schering-Plough HealthCare Products, Inc. **(Primary Predicate)** – K031697
   Histofreezer/17% Salicylic acid-Verruca Plantari, by OraSure Technologies, Inc. **(Predicate - use of 17% salicylic acid – Larger Size Lesions and Plantar Wart Claim; use of an aperature pad)** – K980739
   Dr. Scholl's Clear Away Fast-Acting Liquid Wart Remover, salicylic acid 17% **(Labeling only)**

4. *Description of Device*:
   Dr. Scholl's® Dual Action Freeze Away™ Wart Remover is a cryosurgical system for the over-the-counter removal of common and plantar warts. The device consists of the following:
   a. Pressurized canister with a cryogen mixture of liquid dimethyl ether and propane
   b. Salicylic Acid Liquid Wart Remover
   c. Reusable activator that releases the cryogen into the applicators
   d. Disposable applicators
   e. Cushions
   f. Information booklet

5. *Intended Use Statement:*
   Dr. Scholl's® Dual Action Freeze Away™ Wart Remover is indicated for the over-the-counter removal of common and plantar warts.

6. *Comparison of Technological Characteristics:*
   Dr. Scholl's® Dual Action Freeze Away™ Wart Remover is substantially equivalent to the Dr. Scholl's® Freeze Away™ Wart Remover by Schering-Plough HealthCare Products. The only significant difference between the two products is that the Dr. Scholl's® Dual Action Freeze Away™ Wart Remover contains the liquid wart remover, salicylic acid 17% for post cryo-treatment for the over-the-counter removal of common and plantar warts. For the use of 17% salicylic acid post cryo-treatment,

substantial equivalence is claimed to the Histofreezer/17% Salicylic acid-Verruca Plantari.

Both devices (Freeze Away, Histofreezer) are portable cryosurgical systems comprised of a canister containing cryogen and an applicator that applies the cryogen to the wart to be treated.

a. Laboratory Testing
The average temperature of the Dr. Scholl's® Dual Action Freeze Away™ Wart Remover applicator surface after activation is -42°C.

b. Biocompatibility
The cryogen used is a mixture of dimethyl ether and propane, in the same proportions as the cryogen used in the primary predicate device (Dr. Scholl's® Freeze Away™ Wart Remover).

The standard biocompatibility studies recommended under ISO 10993 for a medical device with limited surface contact duration to breached/compromised skin were conducted on the applicator material.

c. Comparison to Predicate Devices:

Application
Dr. Scholl's® Dual Action Freeze Away™ Wart Remover includes an applicator that freezes the wart to be treated and includes the use of liquid wart remover, 17% salicylic acid as a post cryo-treatment.

The primary predicate device (Dr. Scholl's® Freeze Away™ Wart Remover) uses the same applicator constructed of the same material. The predicate device (Histofreezer/ 17% Salicylic acid-Verruca Plantari) uses the same concentration of liquid wart remover, salicylic acid 17%, post cryo-treatment.

Applicator Effectiveness Duration
Dr. Scholl's® Dual Action Freeze Away™ Wart Remover maintains a temperature of -42°C at the applicator tip for approximately 170 seconds when tested using a temperature probe resting on a room temperature Teflon surface. The primary predicate device (Dr. Scholl's® Freeze Away™ Wart Remover) cryogenic effectiveness is identical.

The effectiveness of cryotherapy plus liquid wart remover, salicylic acid 17% post cryo-therapy for the treatment of common and plantar warts is supported by the predicate device, Histofreezer/17% Salicylic acid-Verruca Plantari.

Cryogen
Dr. Scholl's Dual Action Freeze Away™ Wart Remover uses a cryogen composed of dimethyl ether and propane. The primary predicate device (Dr. Scholl's® Freeze Away™ Wart Remover) uses the same cryogen in the same proportions.

Liquid Wart Remover, Salicylic Acid
Dr. Scholl's® Dual Action Freeze Away™ Wart Remover contains liquid wart remover, salicylic acid 17% as a post cyro-treatment. The predicate device, Histofreezer/17% Salicylic acid-Verruca Plantari is a prescription device that uses the same concentration of liquid wart remover, salicylic acid, 17% for post cryo-treatment for the removal of common and plantar warts. The liquid wart remover, salicylic acid 17% is generally recognized as safe and effective for the removal of common and plantar warts under the Final Rule for Wart Remover Drug Products, 21 CFR 358, Subpart B.

Safety / Ease of Use
Dr. Scholl's® Dual Action Freeze Away™ Wart Remover cryogen unit contains the same safety features as the primary predicate device, Dr. Scholl's® Freeze Away™ Wart Remover. The safety of cryotherapy plus liquid wart remover, salicylic acid 17% post cryo-therapy for the treatment of common and plantar warts is supported by the prescription predicate device, Histofreezer/17% Salicylic acid-Verruca Plantari. Additionally, an Actual Use Study was conducted to support over-the-counter use.

Indications for Use
Dr. Scholl's® Dual Action Freeze Away™ Wart Remover is indicated for the over-the-counter removal of common and plantar warts.

The primary predicate device (Dr. Scholl's® Freeze Away™ Wart Remover) is indicated for the over-the-counter removal of common and plantar warts. The prescription device (Histofreezer/17% Salicylic acid-Verruca Plantari) is indicated for the removal of common warts and plantar warts using liquid wart remover, salicylic acid 17%, as adjunct therapy.

Labeling
The safety and warning statements for the Dr. Scholl's® Dual Action Freeze Away™ Wart Remover are the same as the OTC predicate device (Dr. Scholl's® Freeze Away™ Wart Remover). The labeling has been re-formatted using a bulleted format. Additionally, an Actual Use Study was conducted to ensure adequate directions for use to support the over-the-counter use of the medical device.

7. *Significant Changes or Modifications to Device*

Switch to Over-the-Counter
The Dr. Scholl's® Dual Action Freeze Away™ Wart Remover is a convenient over-the-counter cryogenic treatment for common and plantar warts. This 510(k) submission contains data to document that adequate directions for use have been

established to support the over-the-counter use of this medical device. A Label Comprehension Study was conducted to prior to initiating an Actual Use Study. The Actual Use Study was conducted to evaluate that directions for use are well understood by consumers to help ensure safe use of the cryotherapy device and liquid wart remover, salicylic acid 17%, in treating common and plantar warts under self-treatment conditions (i.e., in the home). The Actual Use Study was conducted among 51 consumers who were asked to use the device according to the labeling in a naturalistic setting without the supervision of a health professional.

The labeling of Dr. Scholl's® Dual Action Freeze Away™ Wart Remover has been developed to ensure the consumer has adequate directions for safe self-use.

8. *Conclusion*
Based on the information presented above, it is concluded that the proposed Dr. Scholl's® Dual Action Freeze Away™ Wart Remover is safe and effective for its intended use when used in accordance with label directions and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 14 2005

Ms. Doreen Frank
Schering-Plough Healthcare Products, Inc.
3 Connell Drive
Berkeley Heights, New Jersey 07922

Re: K052259
Trade/Device Name: Dr. Scholl's Dual Action Freeze Away Wart Remover, Model 4
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH
Dated: November 29, 2005
Received: December 1, 2005

Dear Ms. Frank:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buehrle
for

Mark N. Melkerson
Acting 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): K052259

Device Name: Dr. Scholl's® Dual Action Freeze Away™ Wart Remover

Indications for Use: For the removal of common and plantar warts.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use X (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bruchmann for LWM

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

510(k) Number K052259