

Buchanan Ingersoll

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July 1, 2003

VIA FACSIMILE AND CERTIFIED MAIL

Ms. Michelle M. Jackson
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Re: Alcavis International Inc. Citizen Petition – Docket No. 75N-183H Comment No. CP13

Dear Ms. Jackson:

This letter follows up on our recent correspondence of June 5 and June 17, which reprovided letters (dated December 20, 2002 and March 18, 2003) that Alcavis International had submitted to the Agency for consideration in its review of the above-captioned Citizen Petition. Those letters also identified particular references to that Citizen Petition which address the use of sodium hypochlorite for a material time and to a material extent as a healthcare antiseptic.

In the interest of facilitating your review, I am providing copies of some of those references, described below:

- Reference 31, the Merck Index of 1960, identifies sodium hypochlorite and sodium hypochlorite solution and identifies its use as an antiseptic for irrigation of wounds and urinary bladder and as footbath for prophylaxis against ringworm.
- Reference 33, Handbook of Nonprescription of Drugs, 1977, page 306, addresses sodium hypochlorite and its antimicrobial effect, and its use as a topical antiseptic.
- Reference 36, Remington's Practice of Pharmacy, 1936, page 584, describes its use as a rapid germicide and efficient antiseptic for infected wounds.
- Reference 37, Remington's Practice of Pharmacy, 1961, describes its germicidal action, its ability to dissolve necrotic tissue, and its use in the treatment of suppurated wounds, often by continuous irrigation.
- Reference 40, Modern Drug Encyclopedia and Therapeutic Guide, 1936, page 330, identifies "Hyclorite," a sodium hypochlorite concentrate by Bethlehem Labs with the following uses: surgery . . . in bone suppurations, common ulcers, empyema, abdominal infections, skin grafting and burns; laryngology . . . in throat and ear conditions, in purulent and sinus disease and tonsillar infection; ophthalmology . . . for use in purulent

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July 1, 2003

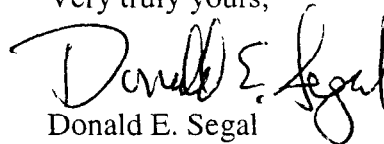
Page 2

conjunctivitis; urology . . .for use in acute and chronic gonorrhea, vaginitis and cystitis, as well as ulcers; dentistry . . . in the treatment of putrescent pulps.

- Reference 42, Blue Book, 1946, page 152, which contains an advertisement, including size and retail price, for Hyclorite, a sodium hypochlorite solution by Bethlehem Laboratories, 300 Century Building, Pittsburgh, Pennsylvania, and describes its use as an antiseptic, deodorant, and germicide.

Alcavis firmly believes that its Citizen Petition, as supported by the references described above, establishes the use of sodium hypochlorite for a material time and to a material extent as a healthcare antiseptic. Accordingly, the Citizen Petition warrants acceptance by FDA for review in the monograph process and thereafter the inclusion of sodium hypochlorite in the monograph.

Very truly yours,

A handwritten signature in black ink that reads "Donald E. Segal". The signature is written in a cursive style with a large, prominent "D" and "S".

Donald E. Segal

Enclosures

cc: Docket No. 75N-183H (with enclosures)
Mr. John M. Taylor (without enclosures)
Mr. Tom Chin (without enclosures)
Mr. Gerald Rachanow (without enclosures)

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