



Better Health
Through Responsible
Self-Medication

NONPRESCRIPTION DRUG MANUFACTURERS ASSOCIATION

Formerly The Proprietary Association

September 30, 1992

William E. Gilbertson, Pharm. D.
Director
Monograph Review Staff
Office of Over-the-Counter Drug Evaluation
Center for Drug Evaluation and Research
Food and Drug Administration, HFN-210
7520 Standish Place, Room 201
Rockville, Maryland 20855

52 OCT -7 PM 1:05

Dear Dr. Gilbertson:

Enclosed is a draft copy of the survey of the membership of the American Academy pertaining to physician-recall of ochronotic cases. This survey has had input from our task group as well as from Dr. Maria Turner (National Cancer Institute), who is chair of the AAD Task Force on Therapeutic Agents.

It is our intention to field this survey in the next several weeks after we have worked out the funding details with the Academy.

Sincerely yours,

R. William Soller, Ph.D.
Senior Vice President
Director of Science & Technology

Enclosure: Draft Survey of AAD on Ochronosis

WS/leb

78N-0065

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LET8

Draft # 4

Physician Survey on Ochronosis

DATE

As part of an ongoing review, pharmaceutical manufacturers, in cooperation with the American Academy of Dermatology, are asking AAD members to answer a series of brief questions on their medical experience with ochronosis. This questionnaire contains 6 questions and should take less than 5 minutes to complete.

This questionnaire asks for no patient identifiers, and your name will not be used in the compilation and presentation of the final survey results.

INSTRUCTIONS:

1. Read the introductory paragraphs entitled "Definition of Terms."
2. Complete the survey questions.
3. Mail the completed form in the enclosed self-addressed envelope.

Upon receipt of your completed questionnaire, your acknowledgement of participation will be sent via first class mail to your office.

Definition of Terms

Exogenous ochronosis is defined as a reportedly rare occurrence manifested by epidermal bluish-gray discolorations due to the application of certain chemicals. The bluish-gray discolorations present themselves as macular sooty pigmentations and macular stippling/small papules, or less frequently as darker deposits and papules and colloid milia. On a differential basis it should be distinguished from dark-colored inflammatory-caused discolorations in dark skin, argyria, hemochromatosis, Addison's disease, porphyria, pellagra and endogenous ochronosis. Definitive medical diagnosis of exogenous ochronosis includes biopsy.

Endogenous ochronosis, on the other hand, is a metabolic disorder unrelated to chemical exposure. It is a systemic, autosomal recessive disorder due to the absence of the enzyme homogentisic acid oxidase. Homogentisic acid accumulates and may polymerize in connective tissue, resulting in bluish-gray discolorations found in the conjunctiva, cornea, eyelids, sclera and pinnae; in areas rich in sweat glands; and in areas where cartilage or tendons have a thin covering of skin, including ears, nasal tip and hands.

Survey questions begin on the next page.

(Continued . . .)

Survey Questions

1. How would you describe the demographics of your practice of dermatology?
____ % White ____ % Black ____ % Hispanic ____ % Asian
2. How many cases of ochronosis have you diagnosed in your practice of dermatology?
 - a. Exogenous ochronosis _____ cases
 - b. Endogenous ochronosis _____ cases
 - c. I have diagnosed no cases to date of ochronosis _____

If the answer to Question #2 is "No Cases To Date" go to Question #4; otherwise go to Question #3.

3. Of the cases of exogenous ochronosis,
 - a. What were the approximate dates of these cases?

 - b. How many of your cases were confirmed by biopsy: _____ (no. cases)
 - c. Were you the only attending physician? ___ Yes ___ No
 - d. Are medical records available for these cases? ___ Yes ___ No
 - e. What was believed to be the causative agent(s) for your cases of exogenous ochronosis?

4. *Thank you for completing the questionnaire. Please send the completed questionnaire in the enclosed self-addressed envelope so that your response can be counted towards the donation to be given to the Academy.*

Name/Address

Date

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE:

FROM: Director
Monograph Review Staff (HFD-810)

SUBJECT: Material for Docket No. 78N-0065

TO: Dockets Management Branch (HFA-305)

The attached material should be placed on public display under the above referenced Docket No.

This material should be cross-referenced to Comment(s) No. _____.

W. E. Gilbertson

William E. Gilbertson, Pharm. D.

Attachment

OCT -7 PM 1:04

11-10-78