



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
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August 9, 2001

International Medical Research
BotanicLab
2900-B Saturn Street
Brea, CA 92821

RE: F01-12980

Dear

In response to your request of July 18, 2001 for information on International Medical Research, dba BotanicLab, Brea, CA.

Enclosed are the records you requested:
Analyst Worksheets w/attachments, Sample 96196 10 Pgs.

The following charges may be included in a monthly invoice:

Reproduction: \$ 1.00 Search: \$ 16.50 Review: \$ 16.50 Total: \$ 34.00

The above total may not reflect final charges for this request. Please do not send payment unless you receive an invoice.

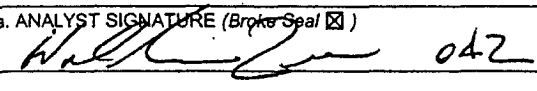
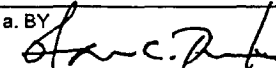
As you will note, the enclosed record(s) contains certain business or personal information that is disclosable only to you or your firm. Copies of these records will be disclosed to other requests only after thorough review and deletion of those portions that are not disclosable to the general public.

Sincerely,


Sandra A. Williams
Paralegal Specialist

CC: HFI-35
 PLEASE ASSESS CHARGES

FLAG Investigational Analysis

ANALYST WORKSHEET		1. PRODUCT PC Spes		2.. SAMPLE NUMBER 96196	
3. SEALS <input type="checkbox"/> NONE <input checked="" type="checkbox"/> INTACT <input type="checkbox"/> BROKEN		4. DATE REC'D 8/22/00	5. RECEIVED FROM Eric Ferguson		6. DISTRICT OR LABORATORY PRL-SW
7. DESCRIPTION OF SAMPLE One brown paper bag identified in part as "96196 8/10/00 KEJ", containing sample. The sample was further contained in a plastic, whirl-pak bag, officially sealed, in part, as "96196 8/10/00 Katherine E. Jacobitz, CSO". The plastic bag was identified as "Sample #96196 08/10/00 KEJ". The sample consisted of the three subunits individually identified, in part, as "96196 08/10/00 KEJ".					
8. NET CON- TENTS	<input type="checkbox"/> NOT APPLICABLE <input checked="" type="checkbox"/> NOT DETERMINED _____ UNITS EXAMINED		DECLARE/UNIT AMOUNT FOUND % OF DECLARED	9. LABEL- ING	_____ ORIGINAL(S) SUBMITTED <u>1</u> COPIES SUBMITTED <input type="checkbox"/> NONE
10. SUMMARY OF ANALYSIS Container: The container was a cylindrical, white, HDPE container with plastic safety-type screw top. The dimensions of the container were: 8.8 cm x 4.6 cm (h x d). Labeling: The label consisted of black, red, green, blue, yellow print on a brown background and black, blue print on white background (attachment F). Code: The lot number, "5430171", was located on the bottom, left-side of the back label. Product: The product was "PC Spes" herbal dietary supplement (attachment F). Analysis (Purpose): Determined the presence of diethylstilbestrol and diethylstilbestrol dipropionate. Method: Analyzed by liquid chromatography(LC)/mass spectrometry(MS). See memo of analysis, page 2. Results: No diethylstilbestrol and diethylstilbestrol dipropionate was detected (page 3).					
11. RESERVE SAMPLE The sample, less the subunit analyzed, was officially sealed as "96196 8/30/00 Walden Lee, Chemist" and returned to Liberty Kaai on 8/30/00.					
12.a. ANALYST SIGNATURE (Broken Seal <input checked="" type="checkbox"/>)  042			13. WORK- SHEET CHECK	a. BY 	
b.				b. DATE 8/3/01	
c.			14. DATE REPORTED 8/3/01		

Instrument Parameters:

Liquid Chromatograph: Hewlett-Packard 1050, 20 mcL sample loop

Time	Flow (mL/min)	%Water	%Methanol
init	.40	40	60
5.00	.40	40	60
15.00	.40	10	90
25.00	.40	40	60
30.00	.40	40	60

Total runtime: 30 minutes.

LC column: Water's XTerra C18, 2.0 x 150 mm

Post column additive: Shidmazu LC 600, MeOH/H2O, 60/40 with .4 % formic acid at .2 mL/min, 1:3 spilt.

Mass Spectrometer:

Finnigan TSQ 700 triple stage quadrupole mass spectrometer w/ electrospray ionization interface operated in the selected ion monitoring mode. Ions scanned were m/z: 135, 238, 269, 325, 381(see attachments A1- A2 for conditions).

Memo of Analysis:

From the sample container, 10 capsules were removed. The contents of the 10 capsules were emptied into a glass mortar and thoroughly mixed using a metal spatula. From this mixture, 0.5 g was weighed into a 50 mL polypropylene (PP) centrifuge tube. To the solid, 15 mL of 50% (v/v) ethanol in water was added. The tube was capped and the solution vortexed for 30 seconds. The sample was centrifuged for 10 minutes at 2500 rpm. The sample was filtered through a .45 mcm glass/nylon filter into a 15 mL PP centrifuge tube and injected into the LC/MS system.

Fortification:

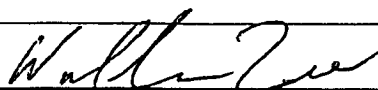
The above method was followed with the following exception. Prior to diluting the sample, the following amounts of each compound was added:

Deithylstilbestrol: 0.7605 mg

Diethylstilbestrol dipropionate: 0.3754 mg

Each compound was detected at 8.12 minutes and 17.68 minutes, respectively (attachment E), when compared with the reference standard injections (attachment C).

ANALYST(S)



ANALYST NO.

042

PAGE 2 OF 3 PAGES

Estimated limit of detection (based on S/N 3:1) :

Diethylstilbestrol 0.0563 mg/mL

Diethylstilbestrol dipropionate 0.00834 mg/mL

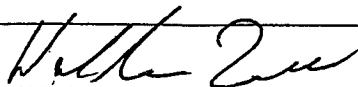
Determination:

1. Inject reference standard (attachment B).
2. Inject blank (attachment C).
3. Inject sample(attachment D).
4. Inject fortification (attachment E).

Conclusion:

Comparison of the standard chromatogram, attachment C, and the sample chromatogram, attachment D, does not indicate the presence of diethylstilbestrol (retention time: 8.11 minutes) and diethylstilbestrol dipropionate (retention time: 17.42 minutes).

ANALYST(S)



ANALYST NO.

042

PAGE 3 OF 3 PAGES