



Diamond Shamrock Chemical Company

A UNIT OF DIAMOND SHAMROCK CORPORATION

Nutrition and Animal Health Division/First and Essex Streets/Harrison, New Jersey 07029/Telephone (201) 484-8400

September 18, 1974

MF 3577

Hearing Clerk
Food and Drug Administration
Room 4-65
5600 Fishers Lane
Rockville, Maryland 20852

Subject: Sponsorship of Zinc Bacitracin and Bacitracin Methylene Disalicylate (Federal Register Notice of August 6, 1974)

Dear Sir:

This is a formal notification to point out a serious oversight in omitting Diamond Shamrock Chemical Company from the proposed list of designated sponsors for zinc bacitracin and for bacitracin methylene disalicylate on Page 28394 of the August 6, 1974 Federal Register.

Since its inception, we have been an active member of the cooperative group in support of the studies on bacitracin and its related compounds required by 21 CFR 135.109. We wish to call attention to the enclosed specific documents and correspondence which we have previously submitted for your files in relation to 21 CFR 135.109 as itemized on the attached sheet under I - Documents; and II - Letters of Authorization.

In consideration of Diamond Shamrock Chemical Company's energetic efforts to comply with the requirements of 21 CFR 135.109 for bacitracin, as documented by the attached list, we strenuously object to our omission from the August 6, 1974 Federal Register proposed list of approved sponsors for bacitracin. We hereby request that immediate steps be taken to add our name to the list of officially approved sponsors for zinc bacitracin and bacitracin methylene disalicylate.

Very truly yours,

DIAMOND SHAMROCK CHEMICAL COMPANY
Nutrition & Animal Health Division

jk
Attachment

Joseph M. McKenna, Ph.D., Manager
Food and Drug Regulatory Affairs

I - DOCUMENTS

<u>Document</u>	<u>Date</u>	<u>Description</u>	<u>Summary of Contents</u>
A	10/16/73	Protocol for <i>in vitro</i> studies and covering letter from AHI addressed to Dr. Gerald Guest	Letter from AHI submitting protocol for <i>in vitro</i> studies on behalf of Diamond Shamrock.
B	1/24/74	Letter from Dr. Guest to C. Ely of Diamond Shamrock	Dr. Guest acknowledges receipt of <i>in vitro</i> protocols and requests that <i>in vivo</i> studies be done
C	2/19/74	<i>In vivo</i> protocols submitted by AHI to Dr. Guest in behalf of Diamond Shamrock Chemical Company	Design of studies to be carried out on poultry, swine and calves.
D	3/14/74	Letter from Dr. Guest to Diamond Shamrock Chemical Company	Dr. Guest acknowledges receipt of Diamond Shamrock's <i>in vivo</i> protocol for salmonella reservoir studies on bacitracin
E	6/26/74	Covering letter and <i>in vivo</i> protocols for bacitracin studies as submitted independently by Diamond Shamrock Chemical Company	The protocols for <i>in vivo</i> studies on bacitracin in relation to the salmonella reservoir are forwarded to Dr. Guest by Diamond Shamrock as a co-sponsor.
F	7/2/74	Letter to Dr. Guest with progress report	Summarizes progress of the <i>in vitro</i> and <i>in vivo</i> studies on the salmonella reservoir using bacitracin
G	8/8/74	Covering letter addressed to Dr. Guest and final report of results of the <i>in vitro</i> studies	Results indicate no development of resistance to bacitracin by organisms exposed to low levels through 20 passages <i>in vitro</i>

II - LETTERS OF AUTHORIZATION

<u>Letter</u>	<u>Date</u>	<u>Description</u>	<u>Contents</u>
#1	10/16/73	Letter signed by [] and addressed to Dr. Guest's Office	Authorizes FDA to refer to [] and other documents in behalf of Diamond Shamrock's submission on zinc bacitracin pre-mixes
#2	10/23/73	Letter signed by [] and addressed to Dr. Gerald B. Guest	Authorizes FDA to refer to [] for safety and efficacy data in behalf of Diamond Shamrock's use of bacitracin methylene disalicylate.