DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Center for Drug Evaluation and Research
Office of Regulatory Policy
Division of Information Disclosure Policy
10903 New Hampshire Ave
BLDG. 51 Room 6214
Silver Spring, Maryland 20993

June 28, 2010

In Response Refer to File: ***2006 - 17871***

Jeffrey Alan Klein, MD Inc.
30280 Rancho Viego Rd.
San Juan Capistrano, CA 92675

Dear Dr. Klein,

This is in response to your FOIA request in which you requested information about Lidocaine with epinephrine for infiltration local anesthesia. Specifically you requested for:

1. An official version of the current FDA approved label for dosage limitations for "lidocaine with epinephrine for infiltration local anesthesia." - Please find the current approved label enclosed.

2. A detailed list the scientific data and publications upon which the current dosage recommendations for Lidocaine with epinephrine are based. -The FDA is no longer required to maintain a list of scientific data and publications upon which dosage recommendations are based. Current dosage recommendations are based on clinical trial and testing data.

3. A copy of the original letter (circa 1947-48) to the FDA from Astra Pharmaceuticals Company upon which the FDA based its approved dosage limitation for lidocaine with epinephrine for infiltration local anesthesia. - Please find enclosed a copy of submissions from Astra to the FDA that resulted in FDA's approval of Lidocaine with epinephrine in 1948.

The DIDP staff and other CDER personnel have spent a significant amount of time searching for the - documents that respond to item 3 of your request. At this point, we have spent a total of 24 hours on search and review time for these records. The fee for the time already spent is approximately $1104.00. If the enclosed documents satisfy your request, we will only charge you up to the $250 limit in your request and keep your request closed. On the other hand, if you want CDER to re-open your request and dedicate additional resources to searching for and redacting more documents, you will need to authorize and pre-pay any estimated fees. We can not guarantee that any additional records will be located. However, you will still be responsible for the cost of the search.

Regarding the enclosures please note that:

Certain material has been deleted from the records furnished to you because a preliminary review of the records indicated that the deleted information is not required to be publicly disclosed and that disclosure is not appropriate. FDA has taken this approach to facilitate the process of responding to you. If you dispute FDA's preliminary determination and would like FDA to reconsider a particular deletion, please let us know in writing at the address listed below within 30 days from the date of this letter. If we do not receive a response in that time period, we will consider the matter closed. If you do request further consideration and if the agency then formally denies your request for any or all of the previously-withheld information, you will have the right to appeal that decision. Any letter of denial will explain how to make this appeal. Responses can be mailed to the address below:

Food and Drug Administration
Office of Management Programs
Division of Freedom of Information
5600 Fishers Lane, (HFI-35)
Rockville, Maryland 20857

The following charges may be included in a monthly invoice:

Reproduction: $4.00 Search: 184.00 Review: $46 Other: $0 TOTAL: $234.00

The above total may not reflect final charges for this request.

PLEASE DO NOT SEND PAYMENT UNLESS YOU RECEIVE AN INVOICE FOR THE TOTAL MONTHLY FEE.

If there are any problems with this response, please notify us in writing of your specific problem(s). Please reference the above file number.

This concludes the response for the Center for Drug Evaluation and Research. If I can be of further assistance to you, please do not hesitate to contact me.

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Enclosure: (40 pages)