GlaxoSmithKline

Dockets Management Branch (HFA-305) 8138 '01 FEB 27 P12:46
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

GlaxoSmithKline
PO Box 13398
Five Moore Drive
Research Triangle Park
North Carolina 27709

Tel. 919 483 2100
www.gsk.com

22-Feb-2001

Re: Docket No. 00N-1610 / Docket No. 00N-1609 – Response to Proposal Rulemaking

Dear Sir or Madam:

We refer to Docket No. 00N-1609 published in the November 24, 2000 Federal Register, which refers to the Notice of Proposed Rule Making which reaffirms the new drug status and conditions for marketing digoxin products for oral use.

We are in agreement with the Notice as published, and with the associated Proposed Rule in the same Federal Register, Docket No. 00N-1610 (RIN 0910-AC12), regarding the revocation of conditions for marketing of digoxin products for oral use.

We wish to note, and appeal to the Agency that when the proposed effective date of the final rule becomes effective for the revocation of the conditions for marketing digoxin products for oral use, and the submission of NDA's and ANDA's are required, that a reasonable period of time be granted for those manufacturers which currently produce and market digoxin products, to prepare, submit and obtain FDA approval for an NDA or an ANDA.

We request a two-year compliance period for this action based on past FDA reviews and precedence.

It is currently our intention to submit an ANDA for digoxin elixir utilizing data contained in our approved NDA 20-405 for Digoxin Tablets to support this application. Preparation of this ANDA will require consultation with the Cardiovascular and Renal Drugs Advisory Committee regarding format and content as well as suitability of the information to be submitted. Administrative, clerical and paperwork requirements will also be necessary. We believe that the Agency's estimate of 480 hours to accomplish this task, as noted in Section IV of Docket No. RIN 00N-1610 is a gross under estimate of the actual time required. The two-year time period already established by precedent by the Agency for similar circumstances would allow appropriate actions to take place.

We respectfully request inclusion of these comments in the consideration of the final rule for RIN 0910-AC12.

Sincerely,

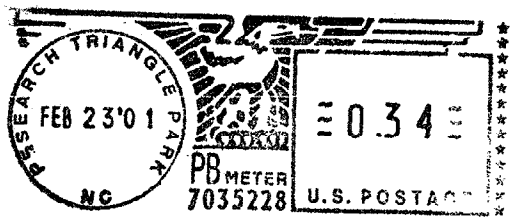
Roger R. Gaby
Product Director
Regulatory Affairs

00N-1609
00N-1610

C 3

GlaxoSmithKline
Five Moore Drive
PO Box 13398
Research Triangle Park
North Carolina 27709-3398

www.gsk.com



Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

20857-0001