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APPROVAL PACKAGE FOR:

APPLICATION NUMBER
20-711/SE8-012

Correspondence

Electronic Mail Message

Date: 2/2/01 1:20:17 PM
From: Benson, Eric (eb35712@GlaxoWellcome.com)
To: 'Judit Milstein 301-827-7410 FAX t- (MILSTEINJ@A1)
Subject: Re: NDA 20-711/S-012 labeling

Dear Judit:

The AK1A4013 study report included in the sNDA documents week 9-12 continuous quit rates of 12% (95%CI, 8-16) and 22% (95%CI,17-27) for placebo and bupropion SR, respectively(see text in Volume 2, page 55 and Supporting Table 8 in Volume 2, page 262 in the application). However, the draft labeling submitted to the agency erroneously stated quit rates of 12% (95%CI,7-16) and 21% (95%ci, 16-26) for placebo and bupropion SR, respectively. The attached labeling is now corrected and is consistent with the previously submitted study report.

We apologize for any inconvenience this may have caused.

<<Zyban PI COPD 2-2-01.doc>>

We would like to proceed with the teleconference scheduled for Wednesday, February 7, 2001 from 3:00 - 4:00 PM. Our objective for that discussion is
'understand the Agency's rationale for removing the results from the
)s allowed" analysis from the Table 3.

I look forward to speaking with you soon and also look forward to the approval of this sNDA.

Sincerely,

Eric Benson
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