

US REGULATORY AFFAIRS: PSYCHIATRY/NEUROLOGY

Monthly Highlights for June 2007

Date: 07/02/2007

KEY UPCOMING ACTION DATES for 2007

Redacted

KEY UPCOMING SUBMISSIONS for 2007

Redacted

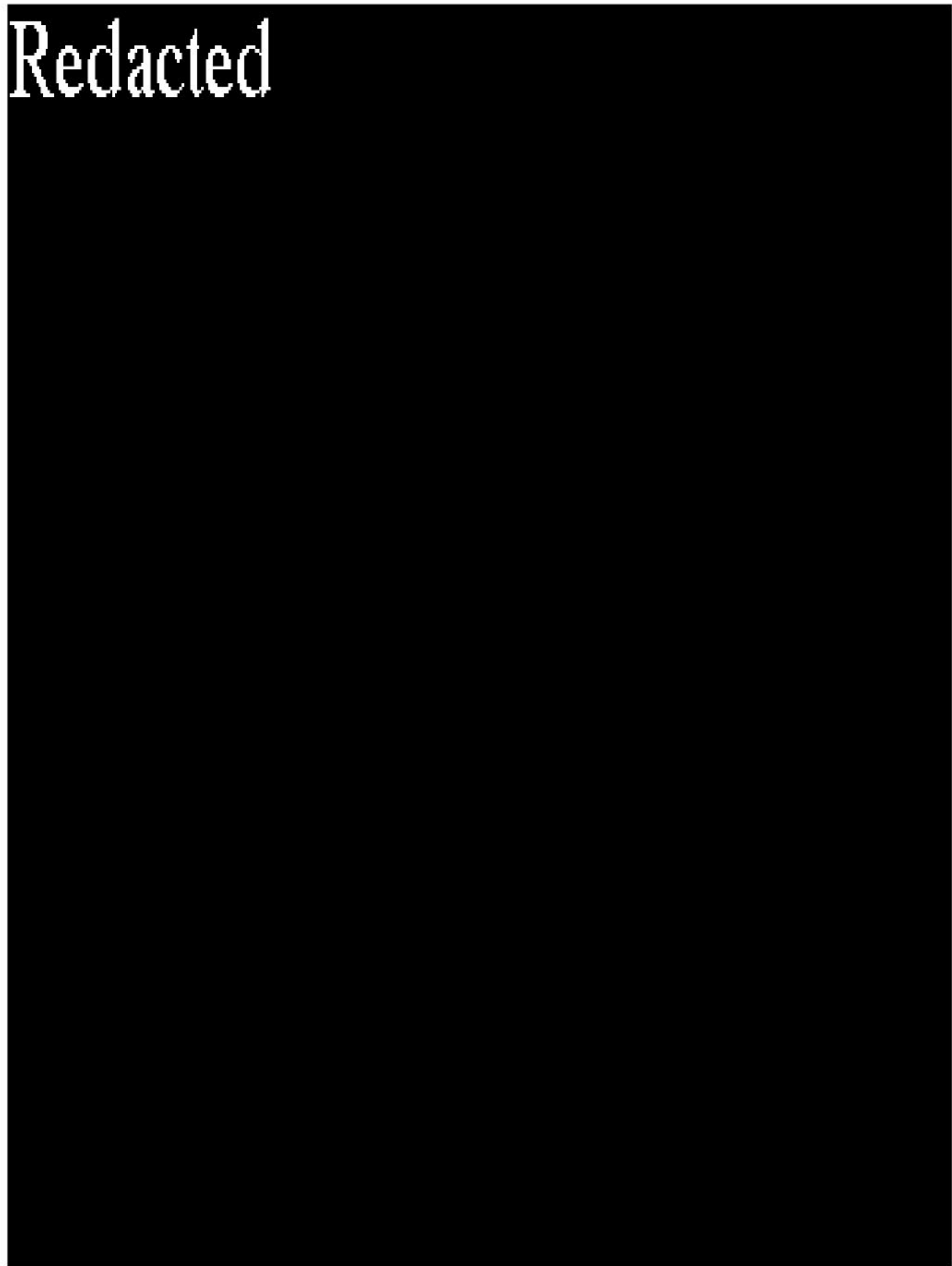
KEY SUBMISSIONS-Status

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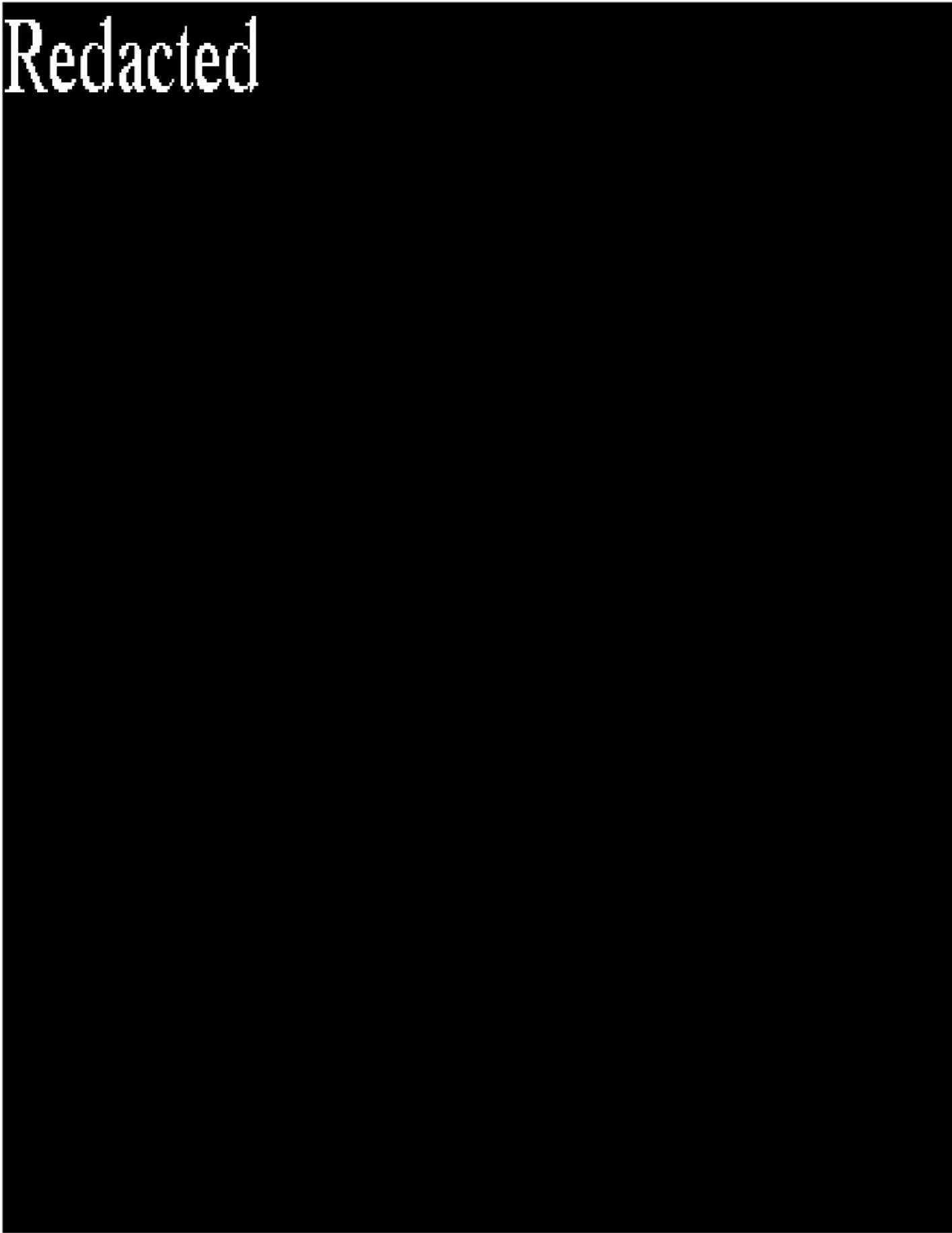
Plaintiff Exhibit
PTX-344

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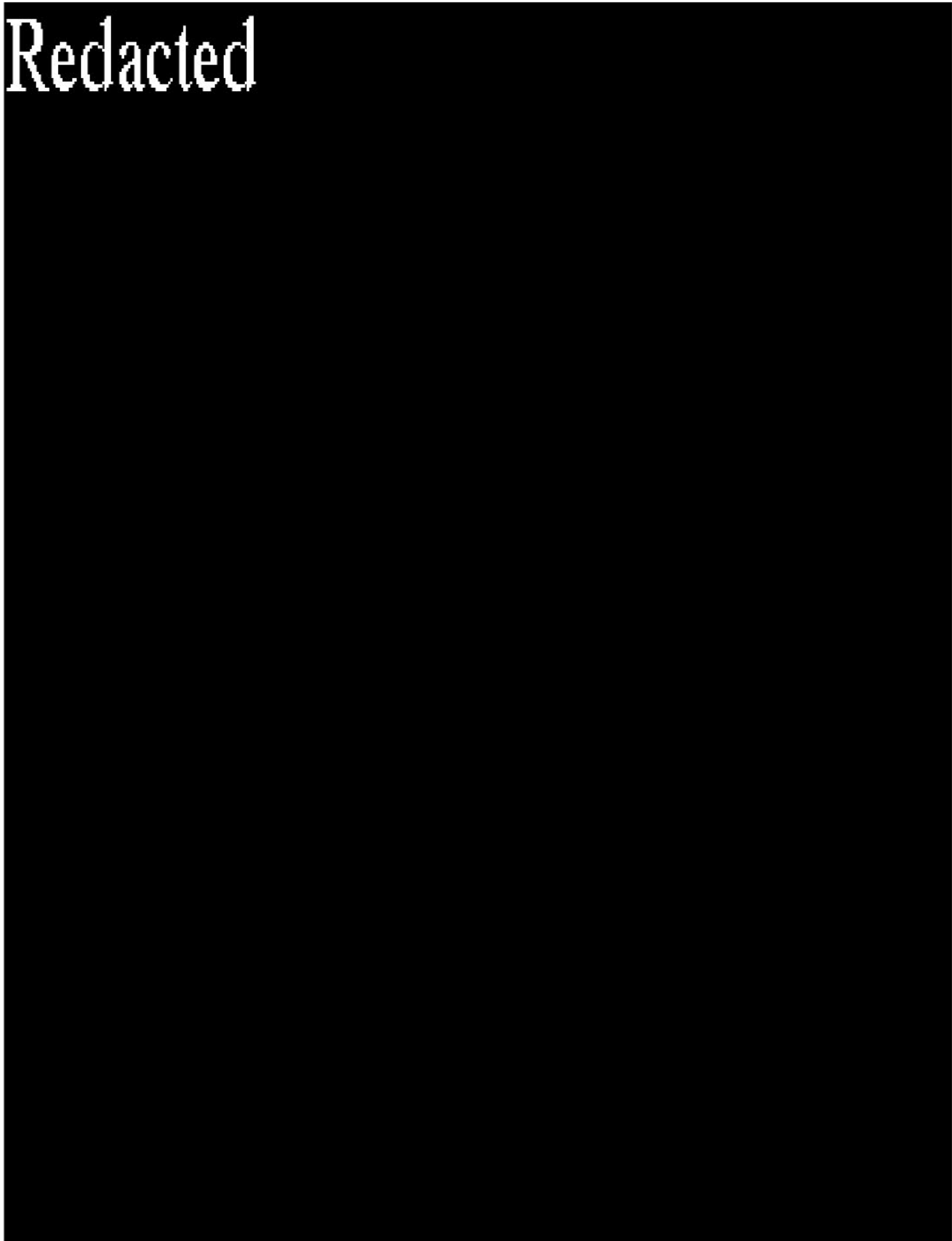
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PSYCHIATRY

Antidepressant Class Labeling Revisions-Suicidality

On June 21, 2007, GSK received additional changes via email from FDA for the antidepressant class label revision regarding young adult suicidality. GSK provided revised labeling incorporating the changes requested by FDA on June 28th for the 4 bupropion products; this new labeling will also be implemented for Paxil and Parnate products.

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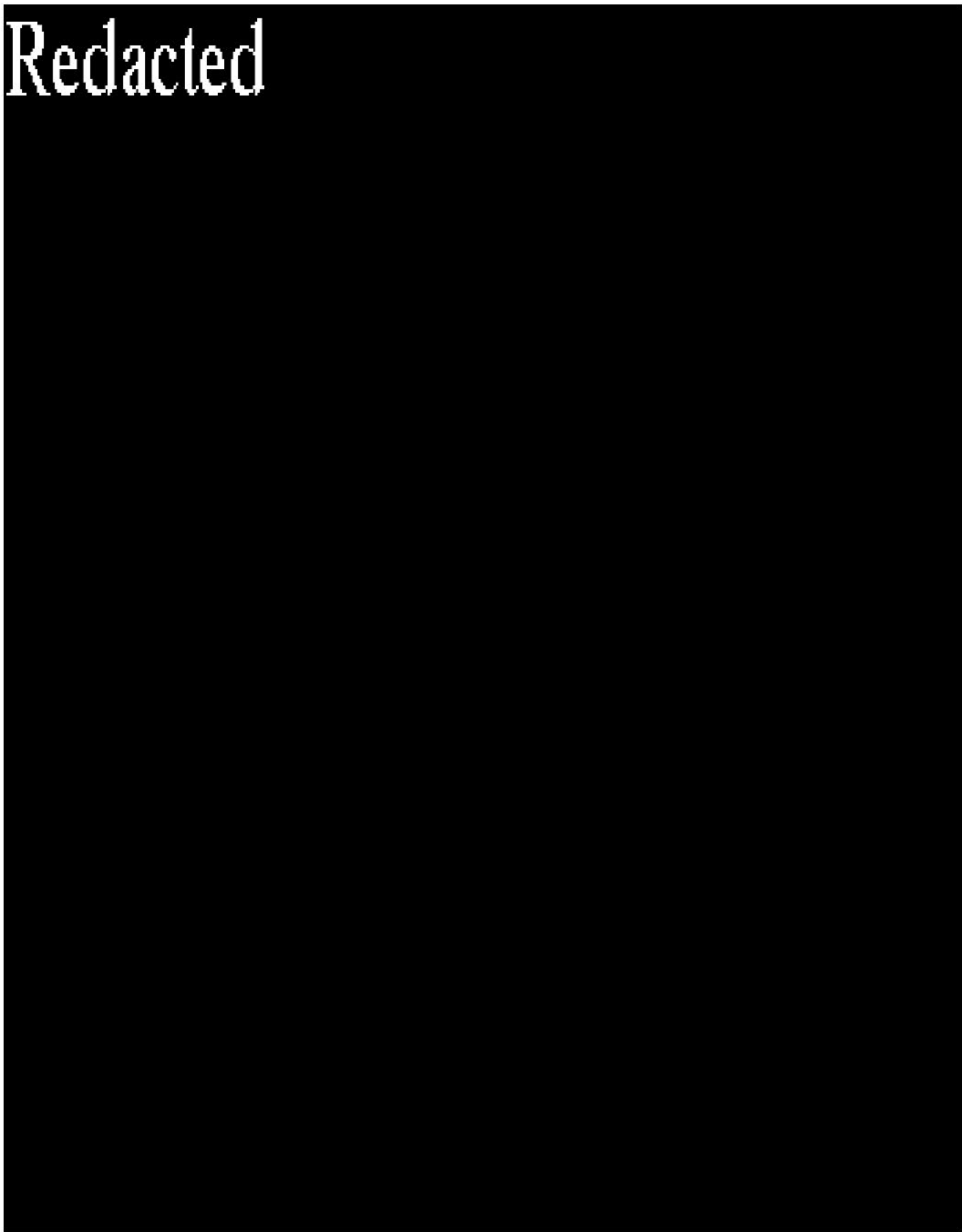
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Paxil:

On June 21, 2007 FDA responded to our CBE submission for Paxil, Paxil CR and Paroxetine (submitted on May 23, 2007). They requested additional changes in the wording of the class labeling (from all sponsors and other GSK drugs as well) and asked for response via email within one week. GSK's request of maintaining the Paxil specific language within the class labeling was not addressed. FDA requested that those additions or changes should be addressed with a separate supplement. In addition FDA confirmed that we would have to ask for a meeting to discuss the option of including Paxil specific language in the label. The teams will coordinate efforts and will respond via email next week and will send word versions via emails for approval.

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Due Diligence Activities

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