Clarification Regarding Generic Substitution for Psychotropic Drugs

To the Editor:

Please be advised that there is an error in the article, "Generic Substitutions for Psychotropic Drugs," which appeared in the September 2009 Supplement to *CNS Spectrums*, Volume 14, Number 9. In several places in the article, statements indicate that a generic formulation is available for escitalopram, and provides a generic availability date of 2006. These statements are incorrect. In fact, at this time, no generic formulation is commercially available for Lexapro (escitalopram) in the United States. Forest Laboratories retains patent/exclusivity for Lexapro until March 2012.[1]

These statements appear on the following pages: Focus Points section (page 1), the text of the response to question 1 (pages 2–3) and the Table (page 3). The corrected text for these statements is provided below:

- On page 1, Focus Points section, bullet 1, the corrected statement should read: "Many psychotropic agents currently in use are available as generic products—including citalopram, fluoxetine, paroxetine, sertraline, and venlafaxine."

- On page 2, column 2, paragraph 4, lines 5–7, continuing on page 3, column 1, paragraph 1, lines 1–2, the corrected statement should read: "With the exception of escitalopram, for which no generic formulation is currently available in the US, each of the selective serotonin reuptake inhibitors is off-patent and is available as a generic product, including fluoxetine (since 2001), paroxetine (since 2003), citalopram (since 2004), and sertraline (since 2006).[1,17]"

- On page 3, the Table, "Antidepressants and Antipsychotics," line 2 under the category SSRIs, the corrected text for the Generic Approval of Lexapro (escitalopram) should read: "N/A" (for not applicable).

Finally, in an effort to avoid future disparities between the dates provided for generic approval in this Supplement and the dates when the generic formulation becomes commercially available, the Table (see page 710) has been updated to provide generic approval dates only for those cases in which a generic formulation currently is available. For drugs for which no generic currently is available, the table simply states "N/A" for not applicable.

Sincerely,
Pierre Blier, MD, PhD

REFERENCE

1. Food and Drug Administration Electronic Orange Book. Approved Drug Products With Therapeutic Equivalence Evaluations. Patent and Exclusivity Search Results from query on Appl No 021323 Product 001 in the OB_Rx list. Available at: www.accessdata.fda.gov/scripts/cder/ob/docs/patexclnew.cfm?Appl_No=021323&Product_No=001&table1=OB_Rx. Accessed November 19, 2009.

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TABLE
Antidepressants and Antipsychotics[1]

Brand (Generic)	Brand Approval	Generic Approval*
SSRIs		
Celexa (citalopram)	July 1998	October 2004
Lexapro (escitalopram)	August 2002	N/A
Paxil (paroxetine) IR	December 1992	July 2003
Paxil (paroxetine) CR	February 1999	June 2007
Prozac (fluoxetine)	December 1987	August 2001
Zoloft (sertraline)	December 1991	June 2006
SNRIs		
Effexor (venlafaxine) IR	December 1993	August 2006
Effexor (venlafaxine) XR	October 1997	May 2008†
Cymbalta (duloxetine)	August 2004	N/A
Pristiq (desvenlafaxine)	February 2008	N/A
Other Antidepressants		
Remeron (mirtazapine)	June 1996	January 2003
Remeron (mirtazapine) ODT	January 2001	December 2003
Wellbutrin (bupropion) IR	December 1985	November 1999
Wellbutrin (bupropion) SR	October 1996	November 2003
Wellbutrin (bupropion) XL	August 2003	December 2006
Atypical Antipsychotics		
Abilify (aripiprazole)	November 2002	N/A
Abilify (aripiprazole) ODT	June 2006	N/A
Clozaril (clozapine)	September 1989	November 1997
Fazaclo (clozapine) ODT	February 2004	N/A
Geodon (ziprasidone)	February 2001	N/A
Invega (paliperidone)	December 2006	N/A
Risperdal (risperidone)	December 1993	June 2008
Risperdal (risperidone) ODT	April 2003	February 2009
Saphris (asenapine)	August 2009	N/A
Seroquel (quetiapine)	September 1997	N/A
Seroquel (quetiapine) XR	May 2007	N/A
Zyprexa (olanzapine)	September 1996	N/A
Zyprexa (olanzapine) Zydis	April 2000	N/A

* Earliest date of generic approval by the US FDA is listed for compounds for which a generic is commercially available; N/A is stated for brands for which no generic is commercially available.

† The US FDA approved a generic venlafaxine extended-release tablet that is bioequivalent but not therapeutically equivalent, and therefore not routinely substitutable for Effexor XR.

SSRIs=selective serotonin reuptake inhibitors; IR=immediate release; CR=controlled release; SNRIs=serotonin norepinephrine reuptake inhibitors; XR=extended release; NCE=new chemical entity; ODT=orally disintegrating tablet; SR=sustained release; XL=extended release; N/A=not applicable; NDF=new dosage formulation.

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