

# Child & Adolescent Bipolar Foundation

Education, Support and Advocacy for Children, Adolescents and Families [www.bpkids.org](http://www.bpkids.org)

3378 02 JUL 16 18:19

EXECUTIVE DIRECTOR  
Martha Hellander, J.D.

PRESIDENT  
Ruth Field

BOARD OF DIRECTORS  
Ann Baumbach  
Robert Field, C.P.A., C.F.P.  
Barbara Geller, M.D.  
Dorie Geraci, M.S., R.N.  
Marjorie Kitzes, M.Ed.  
Tricia Kratz  
Marcie Lipsitt  
William MacDonald, C.P.A.  
Ellen Solms  
Susan R.F. Solomon, J.D.  
Muffy Walker, R.N., M.S.N.

PROFESSIONAL  
ADVISORY BOARD

Chair  
Barbara Geller, M.D.  
Ross J. Baldessarini, M.D.  
Joseph Biederman, M.D.  
Kiki D. Chang, M.D.  
Edwin H. Cook, Jr., M.D.  
Andrea Eberle, M.D.  
Gianni L. Faedda, M.D.  
Robert L. Findling, M.D.  
David Horrobin, M.D., Ph.D.  
Kay Redfield Jamison, Ph.D.  
Vivian Kafantaris, M.D.  
Robert A. Kowatch, M.D.  
Neal D. Ryan, M.D.

P.M.B. 331  
1187 Wilmette Avenue  
Wilmette, Illinois 60091  
(847) 256-8525  
(847) 920-9498 Fax  
email: cabf@bpkids.org

CABF is a not-for-profit organization. Contributions may be tax-deductible.

July 8, 2002

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

(Via e-mail to: [fdadockets@oc.fda.gov](mailto:fdadockets@oc.fda.gov))

Re: ANPRM Obtaining Timely Pediatric Studies of an Adequate Pediatric Labeling for Human Drugs and Biologics  
(Docket No. 02N-0152, 4-24-02)

### To Whom it May Concern:

The Child & Adolescent Bipolar Foundation (CABF) is a not-for-profit organization of over 5,500 families raising children diagnosed with, or at risk for, early onset bipolar disorder (manic-depressive illness). Medications used to treat our children are generally used off-label and have not been tested in children for this indication, if at all.

CABF believes that the voluntary provisions for pediatric exclusivity and the NIH funding mechanism to contract for needed studies, as provided in the Best Pharmaceuticals for Children Act (BPCA), are insufficient to ensure that drugs used for children will be studied in children. We urge that the Pediatric Rule remain in force so that the FDA may require pediatric testing of drugs in appropriate cases that fall outside these mechanisms.

CABF supports maintaining pediatric exclusivity incentives, but urges the FDA to require amendment of drug labeling to include additional safety data generated by studies done under the pediatric exclusivity provision, even if the drug is found not effective against placebo for the indication. There is such a tremendous need for more safety information and it is wasteful not to capture information generated from studies under the pediatric exclusive provision and integrate that information into the existing label for the drug.

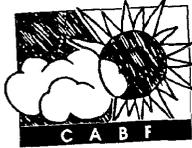
In addition, ~~nothing in the BPCA~~ mentions orphan conditions. In the Orphan Drug Act, children are referred to as "therapeutic orphans." Medications designated to treat orphan conditions (such as pediatric mania) should be accepted for inclusion on the Pediatric List and be eligible for NIH funding in a manner similar to generic products.

02N-0152

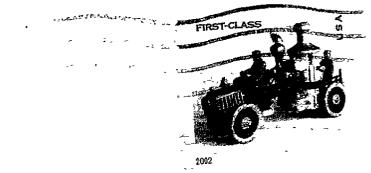
C 134

Respectfully submitted,

Martha Hellander  
Executive Director



P.M.B. 331  
1187 Wilmette Avenue  
Wilmette, Illinois 60091  
[www.bpkids.org](http://www.bpkids.org)



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

20852+0001

