

AMENDMENT TO COMMITTEE PRINT
OFFERED BY MS. ESHOO OF CALIFORNIA
(ped-Rule_004, June 20, 2007)

Page 2, line 3, strike “Section” and all that follows through “follows:” and insert the following new subsection:

1 (a) IN GENERAL.—Section 505B of the Federal
2 Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amend-
3 ed to read as follows:

Strike page 14, line 24, through page 15, line 13,
and insert the following:

4 “(f) REVIEW OF PEDIATRIC PLANS, DEFERRALS,
5 AND WAIVERS.—

6 “(1) REVIEW.—Beginning not later than 30
7 days after the date of enactment of the Pediatric
8 Research Equity Act of 2007, the Secretary shall
9 utilize an internal committee to provide consultation
10 to reviewing divisions on all pediatric plans and as-
11 sessments prior to approval of an application or sup-
12 plement for which a pediatric assessment is required
13 under this section and all deferral and waiver re-
14 quests granted pursuant to this section. Such inter-

1 nal committee shall include employees of the Food
2 and Drug Administration, with expertise in pedi-
3 atics (including representation from the Office of Pe-
4 diatric Therapeutics), biopharmacology, statistics,
5 chemistry, legal issues, pediatric ethics, and the ap-
6 propriate expertise pertaining to the pediatric prod-
7 uct under review, and other individuals designated
8 by the Secretary.

Strike page 15, line 24, through page 16, line 5, re-
designate paragraphs (5) and (6) as paragraphs (6) and
(7) respectively, and insert on page 16, after line 5, the
following:

9 “(4) REVIEW OF PEDIATRIC PLANS, DEFERRALS
10 AND WAIVERS.—Consultation on pediatric plans and
11 assessments by the internal committee pursuant to
12 this section shall occur prior to approval of an appli-
13 cation or supplement for which a pediatric assess-
14 ment is required under this section. The internal
15 committee shall review all requests for deferrals and
16 waivers from the requirement to submit a pediatric
17 assessment granted under this section and shall pro-
18 vide recommendations as needed to reviewing divi-
19 sions.

20 “(5) RETROSPECTIVE REVIEW OF PEDIATRIC
21 PLANS, DEFERRALS AND WAIVERS.—Within one year

1 after enactment of this Act, the committee shall con-
2 duct a retrospective review and analysis of a rep-
3 resentative sample of assessments submitted and de-
4 ferrals and waivers approved under 505B since en-
5 actment of the Pediatric Research Equity Act of
6 2003. Such review shall include an analysis of the
7 quality and consistency of pediatric information in
8 pediatric assessments and the appropriateness of
9 waivers and deferrals granted. Based on such review,
10 the Secretary shall issue recommendations to the re-
11 view divisions for improvements and initiate guid-
12 ance to industry related to the scope of pediatric
13 studies required under 505B.

Page 20, line 12, insert after “If” the following: “,
on or after the date of enactment of the Pediatric Re-
search Equity Act of 2007,”.

Page 23, lines 18, strike the period and insert “and
labeling changes made as a result of such studies.”.

Page 24, after line 6, insert the following new sub-
section:

14 (b) APPLICABILITY.—The amendment made in sub-
15 section (a) applies to assessments required under section
16 505B on or after the date of enactment of this Act.

Page 26, strike lines 9 through 11.