

Chuck Grassley
S.L.C.

PENDING

AMENDMENT NO. _____ Calendar No. _____

Purpose: To provide for the application of stronger civil penalties for violations of approved risk evaluation and mitigation strategies.

IN THE SENATE OF THE UNITED STATES—110th Cong., 1st Sess.

S. 1082

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By *Brown for Grassley* AMENDMENT No. 0998 to
To: *5.1082* fee

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Page(s)

GPO: 2006 30-772 (Mac)

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

1 At the appropriate place in section 505(o) of the Fed-
2 eral, Food, Drug, and Cosmetic, as added by section 202,
3 insert the following:

4 “(9) CIVIL MONETARY PENALTY.—Notwith-
5 standing any other provision of this Act, an appli-
6 cant (as such term is defined for purposes of this
7 section) that knowingly fails to comply with a re-
8 quirement of an approved risk evaluation and miti-
9 gation strategy under this subsection shall be subject

1 to a civil money penalty of \$250,000 for the first
2 30-day period that the applicant is in noncompli-
3 ance, and such amount shall double for every 30-day
4 period thereafter that the requirement is not com-
5 plied with, not to exceed \$2,000,000.”.