

Chuck Grassley

S.L.C.

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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

Brown for AMENDMENT No. 0998

To an By *Grassley* to
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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.”.