

NO *Lucy*
Rain's
Butler } *UCCO*

AMENDMENT TO H.R. 1937 RE: "SIZE, SHAPE AND COLOR"

OFFERED BY MR. FRANK

On page 8, add the following new section:

SECTION 2: Title 21 of the U.S. Code is amended by adding the following new subsection after subsection (k):

"(1) Notwithstanding any other provision of Federal or State law (excepting subsequent Federal laws referring to this subsection), if a drug product is marketed pursuant to a Federal approval under this Title, the manufacturer, distributor, or dispenser of the product shall not, on account of the product's size, shape, color, or appearance characteristics (other than the imprint of a trademarked name or symbol, or an FDA number), be liable to claims that (a) the product directly, indirectly or in a contributory fashion infringes upon any proprietary rights, under federal, state, or common law, of any manufacturer or distributor of a competitive product, or (b) it otherwise represents in a false and misleading manner the identity, source or origin of the product."

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AMENDMENT TO H.R. 1937

OFFERED BY MR. FRANK

All-time
would
be 10 1/2
mths.

Page 2, line 22, insert before the period the following:
'', except that in the case of a patent for a new drug, the
term of the patent shall not be extended for more than three
years''.

Page 5, line 10, strike out ''new drug,''

Page 6, insert after line 9 the following:

1 ''(B) with respect to a product which is a new
2 drug (as that term is defined in section 201 of the
3 Federal Food, Drug, and Cosmetic Act), a period
4 beginning with the filing of an application for the
5 drug under section 505(b) of such Act and ending on
6 the date the application is approved, which period--

7 ''(i) shall be established by an order
8 issued by the Secretary of Health and Human
9 Services after a proceeding before the Secretary
10 in which the holder of the patent for the drug
11 shall establish the filing and approval dates
12 and shall demonstrate that the holder of the
13 patent acted with reasonable diligence to secure
14 such approval; and

15 ''(ii) shall be reduced by any period
16 between the filing and approval of the

1 application during which, as determined by the
2 Secretary, the holder of the patent did not act
3 with reasonable diligence to secure approval of
4 the application;

Redesignate the succeeding subparagraphs accordingly.