AMENDMENT TO COMMITTEE PRINT
OFFERED BY MR. ROSS OF ARKANSAS

(PDUFA_004; June 20, 2007)

Add at the end the following:

1 **SEC. ___. TREATMENT OF LEGACY DRUGS.**

2 The Federal Food, Drug, and Cosmetic Act is amend-
3 ed by inserting after section 523 the following new section:

4 **"SEC. 524. LEGACY DRUGS.**

5 "(a) DEFINITION.—For purposes of this section, a
6 drug shall be deemed a 'legacy drug' if it—

7 "(1) is a prescription-only pharmaceutical prod-
8 uct;

9 "(2) contains no drug components that have
10 not been, alone or in some combination, marketed in
11 the U.S. for at least 25 years prior to January 1,
12 2008, or are not identical, related, or similar (in this
13 section referred to as 'IRS') to at least one drug
14 compound which has been marketed in the U.S. for
15 at least 25 years prior to January 1, 2008;

16 "(3) is composed of active pharmaceutical in-
17 gredients (in this section referred to as 'APIs')
18 which are generally recognized and used by licensed
19 medical professionals (such as physicians, dentists,

1 nurses, and pharmacists) as documented in peer-re-
2 viewed professional literature articles;
3 "(4) is not an injectable or parenteral drug;
4 "(5) is not labeled for use in children under 2
5 years of age unless the required additional studies
6 are performed and use under 2 years of age is ap-
7 proved by FDA; and
8 "(6) contains one or more previously approved
9 API in combination with one or more drug products
10 covered by the OTC monographs issued by FDA.
11 "(b) API COMPONENTS.—Any API component of the
12 drug must have been marketed in the United States prior
13 to December 31, 2007.
14 "(c) COMPLIANCE OF NEW DRUGS.—All drug prod-
15 ucts, including drug products IRS to legacy drugs or
16 changes in the formulations of legacy drugs, introduced
17 into the U.S. market after January 1, 2008, must comply
18 with the marketing approval requirements under sections
19 501 through 510.
20 "(d) APPLICATION OF APPROVAL PROCESS.—
21 "(1) IN GENERAL.—For any drug that meets
22 the criteria of a 'legacy drug' as of July 1, 2008,
23 and which has not otherwise been approved by the
24 Secretary in accordance with the Act, such drug

1 shall be subject to the approval process set forth
2 herein.
3 "(2) EVALUATION.—In evaluating a legacy
4 drug for approval, the Secretary shall promulgate
5 regulations which outline the conditions under which
6 the Secretary shall be required to approve legacy
7 drugs when there is substantial evidence of the his-
8 torical use in reports and studies in peer reviewed
9 medical literature and other similar studies and
10 data.
11 "(e) CONDITIONAL MARKETING.—Any sponsor of a
12 drug filing an application for approval of a legacy drug
13 may continue to market the drug during the drug applica-
14 tion process, if the sponsor meets the following criteria:
15 "(1) The sponsor shall submit safety informa-
16 tion to the Secretary, including, but not limited to,
17 peer-reviewed literature regarding the safety and ef-
18 ficacy of the drug, appropriate textbooks, medical
19 literature, history of the drug"s use.
20 "(2) The sponsor must submit a Conditional
21 Marketing Package (in this section referred to as a
22 'CMP') to the Secretary. The CMP must include the
23 following:
24 "(A) A full description of product along
25 with copies of all proposed product labeling.

1 "(B) A proposed development plan.
2 "(C) A submission filing plan.
3 "(D) That no known safety issues exist for
4 the product being submitted.
5 "(3) Within 90 days after submission of the
6 safety information and the CMP, the Secretary shall
7 review the CMP and take one of the following ac-
8 tions:
9 "(A) Approve the CMP as submitted.
10 "(B) Provide instructions to the sponsor
11 regarding any changes that must occur to the
12 CMP before it can be approved, including any
13 labeling changes.
14 "(C) Deny the CMP.
15 "(f) RESPONSE TO DENIED CMP.—Any sponsor
16 whose CMP is denied or who refuses to make any re-
17 quested labeling changes may either withdraw the applica-
18 tion for the CMP or file an appeal. If the sponsor chooses
19 to make all changes required by the Secretary to the CMP,
20 including any labeling changes, the sponsor shall have 90
21 days within which to make all required changes, during
22 which time the sponsor shall be allowed to continue mar-
23 keting the product during the approval process. Upon
24 making all required changes, the CMP shall be deemed

1 approved, and the drug may be marketed in accordance
2 with the revised CMP.

3 "(g) DEADLINE FOR SUBMITTAL OF APPLICATION.—
4 The sponsor must submit an application for approval of
5 the legacy drug within 360 days of FDA"s approval of
6 the conditional marketing status of the drug. The Sec-
7 retary may, in its discretion, extend this 360 day period
8 for up to two increments of 180 days, if the sponsor sub-
9 stantiates Clinical Research Organization delays, raw ma-
10 terial import delays, unavailability of subjects for testing,
11 or for any other reason that in the opinion of the Secretary
12 justifies such delay. The Secretary may only grant such
13 extensions if the Secretary determines that the sponsor is
14 continuing its efforts toward submission of its application
15 package for the drug.

16 "(h) UPDATES.—The applicant will provide the Sec-
17 retary with periodic updates of the status of the applica-
18 tion if requested by Secretary. The Secretary shall have
19 the authority to request such updates no more than every
20 six months.

21 "(i) EXCLUSIVITY PERIOD.—Upon the submission
22 and approval of a legacy drug, the applicant shall be pro-
23 vided a market exclusivity period which shall commence
24 as follows:

1 "(1) The first application for a particular leg-
2 acy drug, which is approved by the Secretary, shall
3 be entitled to an exclusivity period, which period is
4 dependent on the required study costs (including
5 bioavailability, toxicity, efficacy, drug-drug inter-
6 action). The exclusivity period shall be the period of
7 not less than 7 years.

8 "(2) Any subsequent application for the same
9 formulation or similar formulation as set forth in
10 paragraph (4) which is accepted by the Secretary
11 within twelve months of the Secretary's acceptance
12 of the original approved application shall be entitled
13 to an exclusivity period equal to the remaining pe-
14 riod of the first application's exclusivity period.

15 "(3) Any application for a particular legacy
16 drug submitted and accepted by the Secretary after
17 twelve months of the original application may be ap-
18 proved by the Secretary but the product could not
19 be marketed until after expiration of the original ex-
20 clusivity period. In the event that another applicant
21 has initiated the process twelve months or more be-
22 fore the date that the current application has been
23 submitted, the current applicant will be notified of
24 same.

1 "(4) Such exclusivity applies to all strengths of
2 the same dosage form that contain the same active
3 ingredient (or ingredients). All products containing
4 the same active ingredient (or ingredients) in the
5 same dosage form in the market on the day of ap-
6 proval of an application would have to exit the mar-
7 ket. However, existing inventories of non-complying
8 products may be shipped from the marketer to their
9 respective wholesale customers for a period of 90
10 days following the approval of the initial product.
11 Attempts to load the trade channels by virtue of spe-
12 cial pricing, dating, or other methods of adding to
13 the pipeline quantity will negate the grace period
14 and the offending company may be required to cease
15 shipments immediately and to recall overshipments
16 from the wholesale channels.
17 "(j) THIRD PARTY PANEL REVIEW.—
18 "(1) MEMBERSHIP.—For purposes of deter-
19 mining which legacy drugs should be approved by
20 the Secretary, the Secretary shall appoint to a panel
21 persons who are qualified by training and experience
22 to evaluate the safety and effectiveness of the drugs
23 to be referred to the panel and who, to the extent
24 feasible, possess skill in the use of, or experience in
25 the development, manufacture, or utilization of, such

1 drugs. The Secretary shall make appointments to
2 each panel so that each panel shall consist of mem-
3 bers with adequately diversified expertise in such
4 fields as clinical and administrative medicine, bio-
5 logical and physical sciences, and other related pro-
6 fessions. In addition, each panel shall include as
7 nonvoting members a representative of consumer in-
8 terests and a representative of interests of the drug
9 manufacturing industry. Scientific, trade, and con-
10 sumer organizations shall be afforded an opportunity
11 to nominate individuals for appointment to the pan-
12 els. No individual who is in the regular full-time em-
13 ploy of the United States and engaged in the admin-
14 istration of this Act may be a member of any panel.
15 The Secretary shall designate one of the members of
16 each panel to serve as chairman thereof.
17 "(2) COMPENSATION.—Panel members (other
18 than officers or employees of the United States),
19 while attending meetings or conferences of a panel
20 or otherwise engaged in its business, shall be enti-
21 tled to receive compensation at rates to be fixed by
22 the Secretary, but not at rates exceeding the daily
23 equivalent of the rate in effect for grade GS-18 of
24 the General Schedule, for each day so engaged, in-
25 cluding travel time; and while so serving away from

1 their homes or regular places of business each mem-
2 ber may be allowed travel expenses (including per
3 diem in lieu of subsistence) as authorized by section
4 5703 of title 5, United States Code for persons in
5 the Government service employed intermittently.

6 "(3) REFERRAL OF APPLICATIONS.—The Sec-
7 retary shall refer the application to an advisory com-
8 mittee of experts established pursuant to paragraph
9 (1) for a report and recommendation with respect to
10 the application. The panel shall, after independent
11 study of the data and information furnished to it by
12 the Secretary and other data and information before
13 it, submit to the Secretary a report and rec-
14 ommendation, together with all underlying data and
15 information and a statement of the reasons or basis
16 for the recommendation. A copy of such report shall
17 be promptly supplied by the Secretary to the appli-
18 cant.

19 "(4) PROVISION OF REPORT.—The Secretary
20 shall provide the applicant with the report and rec-
21 ommendation made by an advisory committee with
22 respect to an application and shall by order, stating
23 the reasons therefor, either affirm the decision re-
24 garding the application referred to the advisory com-
25 mittee or reverse such decision.

1 "(5) PROVISION OF ASSISTANCE.—The Sec-
2 retary shall furnish each panel with adequate clerical
3 and other necessary assistance.
4 "(6) MEETINGS.—Legacy drug panels shall be
5 scheduled to meet at such times as may be appro-
6 priate for the Secretary to meet applicable statutory
7 deadlines.
8 "(7) RIGHTS.—Any person whose drug is spe-
9 cifically the subject of review by a classification
10 panel shall have—
11 "(A) the same access to data and informa-
12 tion submitted to a classification panel (except
13 for data and information that are not available
14 for public disclosure under section 552 of title
15 5, United States Code) as the Secretary;
16 "(B) the opportunity to submit, for review
17 by a classification panel, product specific infor-
18 mation that is based on the data or information
19 provided in the application submitted under
20 Sections 501 through 510 by the person, which
21 information shall be submitted to the Secretary
22 for prompt transmittal to the classification
23 panel; and
24 "(C) the same opportunity as the Sec-
25 retary to participate in meetings of the panel.

1 "(8) MEETINGS.—Any meetings of a legacy
2 drug panel shall provide adequate time for initial
3 presentations and for response to any differing views
4 by persons whose products are specifically the sub-
5 ject of a classification panel review.
6 "(9) REVIEW OF RECOMMENDATIONS.—After
7 receiving from a legacy drug panel the conclusions
8 and recommendations of the panel on a matter that
9 the panel has reviewed, the Secretary shall review
10 the conclusions and recommendations, shall make a
11 final decision on the matter in accordance with sec-
12 tions 501 through 510 and shall notify the affected
13 persons of the decision in writing and, if the decision
14 differs from the conclusions and recommendations of
15 the panel, shall include the reasons for the dif-
16 ference.
17 "(10) EXEMPTION FROM FEDERAL ADVISORY
18 COMMITTEE ACT.—A legacy drug panel under this
19 subsection shall not be subject to the annual char-
20 tering and annual report requirements of the Fed-
21 eral Advisory Committee Act (U.S.C. Appendix).
22 "(k) LEGACY DRUG PANEL ORGANIZATION AND OP-
23 ERATION.—
24 "(1) APPLICATION REFERRAL.—The Secretary
25 shall refer an application to be approved under this

1 section to an appropriate panel established or au-
2 thorized for its review and for its recommendation
3 respecting the approval of the legacy drug. The Sec-
4 retary shall by regulation prescribe the procedure to
5 be followed by the panel in making its review and
6 recommendation.

7 "(2) RECOMMENDATIONS.—Upon completion of
8 a panel's review of a drug referred to it under para-
9 graph (1), the panel shall submit to the Secretary its
10 recommendation for approval or denial of the drug.
11 Any such recommendation shall contain—

12 "(A) a summary of the reasons for the rec-
13 ommendation;

14 "(B) a summary of the data upon which
15 the recommendation is based; and

16 "(C) an identification of the risks to health
17 (if any) presented by the drug with respect to
18 which the recommendation is made.

19 "(l) PANEL RECOMMENDATION.—Upon receipt of a
20 recommendation from a panel respecting a legacy drug,
21 the Secretary shall—

22 "(1) review panel summary provided pursuant
23 to subsection (k)(2);

1 "(2) approve or deny application based upon
2 the information contained in the panel recommenda-
3 tion; and
4 "(3) notify the sponsor of its decision.".