Fact Sheet

Section-by-Section Summary of The Non-Prescription Drug Modernization Act of 2007

Rep. Henry A. Waxman
Chairman, Committee on Oversight and Government Reform

Section 1: Short Title
The Non-Prescription Drug Modernization Act of 2007

Section 2: Amending or Repealing Monographs
Section 2 provides FDA with explicit expedited rule-making authority to amend or repeal the over-the-counter drug regulations, or "monographs," that set forth the permissible marketing conditions for certain OTC drug products. Traditional rule-making, governed by the Administrative Procedure Act (APA), involves a lengthy process that can take years. Under the APA, before issuing a final rule, federal agencies are first required to issue a proposed rule and allow for a public comment period. Additionally, an agency must publish the final rule 30 days before that rule becomes effective. When FDA has complied with these rule-making procedures, the issuance of final rules typically takes several years, and in some instances has even taken up to 10 years.

The Non-Prescription Drug Modernization Act of 2007 would allow FDA to bypass these procedures and amend or repeal a monograph in a more timely fashion in two circumstances:

1) When FDA, on its own initiative, finds that a monograph must be amended or repealed because a drug under the monograph may pose a significant risk; or

2) After a meeting of one of the Agency's Advisory Committees, when FDA finds that a drug under the monograph lacks evidence of effectiveness.

Section 3: Expansion of FDA's Authority to Regulate Drug Advertising
Section 3 provides FDA with the authority to regulate over-the-counter drug advertisements. Currently, FDA regulates advertisements for prescription drugs, while FTC regulates advertisements for over-the-counter drugs.

Section 3 also amends current law to provide that civil monetary penalties for direct-to-consumer prescription drug advertisement violations (which were recently enacted as part of the FDA Amendments Act of 2007) also apply to violative advertisements of over-the-counter drugs.

Section 4: Identification and Report on Monographs
Section 4 requires FDA to identify whether any current monographs are outdated and therefore in need of amendment or repeal. Specifically, Section 4 requires FDA to open a docket to receive comments from the public, including medical societies and scientists, to gather their views on any changes or updates that should be made to products regulated under FDA's current monograph system. After the comment period has concluded and no later than 2 years after enactment, FDA must report to Congress, identifying any monographs that may require further review to determine whether they should be amended or repealed. FDA's report to Congress must also include an assessment of the resources FDA would need to conduct such

a review and make any necessary changes to the monographs, as well as summarize the comments.

Section 5: Authorization of Appropriations

Section 5 would authorize such sums as may be necessary to carry out the Act.