



## FDA's Safety Reviews of Prilosec and Nexium Find No Evidence of Increased Rates of Cardiac Events

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Statement from the FDA

*Background:* On May 29, 2007 AstraZeneca, the maker of Prilosec (omeprazole) and Nexium (esomeprazole), sent FDA data from two long-term studies in patients with severe gastroesophageal reflux disease (GERD) that were being treated with either Prilosec or Nexium. The studies were designed to assess the effectiveness of treatment with Prilosec, or Nexium, or surgery for severe GERD. Participants were randomly assigned to receive treatment with either a drug (Prilosec in one study and Nexium in the other) or surgery. During the studies, cardiovascular events raised a question about whether long-term use of these drugs increases the risk of heart attacks, heart failure, and heart-related sudden death in patients taking either one of the prescribed drugs compared to patients who received surgical treatment. On Aug. 9, 2007 FDA released an "Early Communication of an Ongoing Safety Review" of these drugs. The agency's initial review determined that there was no increased risk of heart problems associated with long-term use of these drugs. At FDA's request, AstraZeneca submitted a large amount of additional information about these and other studies and FDA undertook a comprehensive review of all available data regarding this potential safety concern. The following represents the agency's current analysis of available data on these medications.

*Current Information:* FDA has completed a comprehensive, scientific review of known safety data for the drugs Prilosec and Nexium. While both of the long-term studies reported to FDA on May 29, 2007 collected safety data, the study protocols did not specify how heart problems, such as heart attacks, were defined or verified. As a result, evaluating the information that was gathered about the safety of both drugs in these studies was challenging. FDA's assessment of the information from the data gathered was further supported by an additional analysis of 14 comparative studies of Prilosec, four of which were placebo-controlled. Although these studies were not specifically conducted to assess the risk of heart problems, and patient follow-up was incomplete, they do not suggest an increased risk of heart problems with the use of Prilosec or its newer formulation Nexium.

Based on everything now known at the agency, the reported difference in the frequency of heart attacks and other heart-related problems seen in the earlier analyses of the two small long-term studies does not indicate the presence of a true effect. Therefore, FDA continues to conclude that long-term use of these drugs is not likely to be associated with an increased risk of heart problems. FDA recommends that health care providers continue to prescribe, and patients continue to use, these products as described in the labeling for the two drugs.