

Appendix F

Pravachol 10 mg Tablets OTC
Advisory Committee Briefing Book

Protocol 800-01-97
Screening site informed consent

Bristol-Myers Squibb has developed this study to compare how a cholesterol lowering medicine (Pravachol®), already approved for prescription use, may be used in a prescription or over-the-counter setting. Information about you, your health, and your cholesterol awareness will be obtained to determine your eligibility for this study and to gather facts from people concerned about their cholesterol levels. If you decide not to take any medicine and not proceed with the study, the information from this questionnaire may be used. If you want to continue after you complete the questionnaire, you will be randomized (by chance) to participate in a study of how Pravachol® may be used in either a prescription or over-the-counter setting. At that time, information about the study and Pravachol® will be explained to you in detail. Everyone who completes this questionnaire will be telephoned after 24 weeks to gather additional information about cholesterol awareness. Your identity will remain confidential at all times. Your participation is strictly voluntary and you are free to leave at any time. By initialing below, you show that you have read this statement and agree to proceed.

Subject Initials: _____ Date: _____ / _____ / _____
Mo. Day Year