References

LAXATIVE DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE; PROPOSED AMENDMENT TO THE TENTATIVE FINAL MONOGRAPH

DOCKET NO. 78N-0368L

(OTC Vol. No. 090TFM6)

REFERENCES:

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2. Comment No. C00100.

3. Comment No. LET45.

4. Comment No. LET46.

5. Adverse Event Reports from 1966 to 2000 for Psyllium Laxative Products (Perdiem, Metamucil, and Serutan) collected by FDA's Office of Compliance, in OTC Vol. 090TFM6.

6. FDA, Office of Postmarketing Drug Risk Assessment (OPDRA) (Project ID (PID) 000607) regarding Psyllium Laxative Products Associated with Esophageal Obstruction and Choking, November 17, 2000, in OTC Vol. 090TFM6.

7. Adverse Event Reports from January 1999 to January 2001 for Overnight Relief PERDIEM and Fiber Therapy PERDIEM collected by FDA's Office of Compliance in January 2001, in OTC Vol. 090TFM6.

8. Adverse Event Reports from October 2000 to January 2002 for Overnight Relief PERDIEM and Fiber Therapy PERDIEM collected by FDA's Office of Compliance in April 2002, in OTC Vol. 090TFM6.

9. FDA , Cases of Esophageal Obstruction Associated with PERDIEM (January 1999 to January 2001), in OTC Vol. 090TFM6.

10. FDA, OPDRA Postmarketing Safety Review (PID D020201) regarding Senokot and Psyllium Laxative Products Associated with Esophageal Obstruction and Choking, May 15, 2002, in OTC Vol. 090TFM6.