

AMENDMENT TO COMMITTEE PRINT OF H.R. 1108
OFFERED BY MR. BUYER OF INDIANA

**Page and line numbers refer to committee print dated March
27, 2008.**

Page 130, after line 25, insert the following (and
make such conforming changes as may be necessary):

1 **“SEC. 921. EFFECTIVE DATE.**

2 “**This chapter shall not become effective until 10**
3 **years after the date of enactment of the Family Smoking**
4 **and Prevention and Tobacco Control Act in order to allow**
5 **the Commissioner of Food and Drugs sufficient time to**
6 **certify that the Food and Drug Administration has in-**
7 **spected every foreign facility engaged in the manufacture,**
8 **preparation, propagation, compounding, or processing (as**
9 **such phrase is defined in section 510(a) of the Federal**
10 **Food, Drug, and Cosmetic Act (21 U.S.C. 360(a)) of**
11 **drugs that are imported into the United States.”.**

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Page 130, after line 25, insert the following (and make such conforming changes as may be necessary):

1 **“SEC. 921. EFFECTIVE DATE.**

2 “**This chapter shall not become effective until 5**
3 **years after the date of enactment of the Family Smoking**
4 **Prevention and Tobacco Control Act in order to allow the**
5 **Commissioner of Food and Drugs sufficient time to certify**
6 **that the Office of Regulatory Affairs of the Food and**
7 **Drug Administration has sufficient staff, resources, and**
8 **technology at the 12 international mail facilities in the**
9 **United States to inspect at least 90 percent of the pack-**
10 **ages of drugs and devices (as defined in section 201 of**
11 **the Federal Food, Drug, and Cosmetic Act (201 U.S.C.**
12 **321)) being imported into the United States through such**
13 **facilities.”.**

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Page 130, after line 25, insert the following (and make such conforming changes as may be necessary):

1 **“SEC. 921. EFFECTIVE DATE.**

2 “**This chapter shall not become effective until 3**
3 **years after the date of enactment of the Family Smoking**
4 **Prevention and Tobacco Control Act in order to allow the**
5 **Commissioner of Food and Drugs sufficient time to certify**
6 **that the Food and Drug Administration will achieve the**
7 **goals identified in the letters described in section 101(c)**
8 **of the Food and Drug Administration Amendments Act**
9 **of 2007 (21 U.S.C. 379g note; relating to the Prescription**
10 **Drug User Fee Amendments of 2007) for the upcoming**
11 **fiscal year.”.**

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5 **Commissioner of Food and Drugs sufficient time to certify**
6 **that the Food and Drug Administration will achieve the**
7 **goals identified in the letters described in section 201(c)**
8 **of the Food and Drug Administration Amendments Act**
9 **of 2007 (21 U.S.C. 379i note; relating to the Medical De-**
10 **vice User Fee Amendments of 2007) for the upcoming fis-**
11 **cal year.”.**