“Radiofrequency Identification
Feasibility Studies and Pilot Programs
for Drugs.” The CPG describes
the agency’s intent to exercise enforcement
discretion, until December 31, 2007,
concerning certain regulatory
requirements to facilitate the
performance of feasibility studies and
pilot programs involving
Radiofrequency Identification (RFID)
tags for drugs. The goal of the CPG is
to allow industry to gain experience with
the use of RFID technology to ensure the
long-term safety and integrity of the U.S.
drug supply.

DATES: You may submit written or
electronic comments at any time.

ADDRESSES: Submit written requests
for single copies of the guidance to
the Division of Compliance Policy (HFC–
230), Office of Enforcement, Food and
Drug Administration, 5600 Fishers
Lane, Rockville, MD 20857. Send one
self-addressed adhesive label to assist
that office in processing your request or
include a fax number to which the
guidance may be sent.

Submit written comments on the
guidance to the Division of Dockets
Management, 5630 Fishers Lane, rm.
1061, Rockville, MD 20857. Submit
electronic comments to http://
www.fda.gov/dockets/ecomments. See
the SUPPLEMENTARY INFORMATION
section for electronic access to the guidance
document.

FOR FURTHER INFORMATION CONTACT: Paul
Rudolf, Office of Policy (HF–11), Food
and Drug Administration, 5600 Fishers
Lane, Rockville, MD 20857, 301–827–
3360.

SUPPLEMENTARY INFORMATION:
I. Background

On February 18, 2004, FDA published
a report entitled “Combating Counterfeit
Drugs” which is available on the FDA
Web site at http://www.fda.gov/oc/
initiatives/counterfeit. In that report
the agency identified RFID technology as
the cornerstone in the fight against
counterfeit drugs and announced our
intention to facilitate the adoption of
RFID technology by participants in the
pharmaceutical supply chain. We also
stated that widespread adoption of RFID
technology was feasible by 2007.

Recently, FDA has received inquiries
focusing on whether certain regulatory
requirements, including those related to
labeling, electronic records, and product
quality, apply to pharmaceutical
manufacturers, repackers, relabelers,
distributors, retailers, or others who
participate in feasibility studies and
pilot programs (collectively “a study” or
“studies”) using RFID tags for drugs.
This CPG describes how we intend to
exercise our enforcement discretion
regarding such studies. The exercise of
such enforcement discretion expires on
December 31, 2007. The goal of this CPG
is to facilitate the performance of RFID
studies and allow industry to gain
experience with the use of RFID.

FDA is issuing this document as a
level 1 guidance consistent with FDA’s
good guidance practices regulation
(§ 10.115 (21 CFR 10.115)). The new
CPG Sec. 400.210 is being implemented
immediately without prior public
comment under § 10.115(g)(2), because
the agency has determined that prior
public participation is not feasible or
appropriate, but comments are welcome
at any time. The agency also thinks that
use of RFID technology is critical to
ensuring the long-term safety and
integrity of the U.S. drug supply and
immediate guidance is needed to
facilitate studies of RFID.

II. Comments

Interested persons may submit to the
Division of Dockets Management (see
ADDRESSES) written or electronic
comments on this guidance document.
Submit two copies of written comments,
except that individuals may submit one
copy. Comments are to be identified
with the docket number found in
brackets in the heading of this
document. The guidance and received
comments may be seen in the Division
of Dockets Management between 9 a.m.
and 4 p.m., Monday through Friday.

III. Electronic Access

An electronic version of this guidance
is available on the Internet at http://
www.fda.gov/ara under “Compliance
Reference.”


John Taylor,
Associate Commissioner for Regulatory
Affairs.

[FR Doc. 04–25545 Filed 11–12–04; 4:32 pm]
BILLING CODE 4810–32–U

DEPARTMENT OF HOMELAND
SECURITY

Citizenship and Immigration Services
Bureau

[CIS No. 2331–04]
RIN 1615–ZA68

Extension of Honduras for Temporary
Protected Status; Correction

AGENCY: Citizenship and Immigration
Services, Department of Homeland
Security.

ACTION: Notice of correction.

SUMMARY: U.S. Citizenship and
Immigration Services (USCIS) is
correcting a notice that was published in
the Federal Register on November 3,
2004 at 69 FR 64084 which announced
the extension of the designation of
Honduras for Temporary Protected
Status (TPS). In the supplemental
information to the notice, USCIS
inadvertently misstated that only Form
I–821 with Revision Date 7/30/04 will
be accepted. However, the Form I–821 Instructions were revised on November 5, 2004 and are now consistent with the filing instructions in the aforementioned Federal Register notice. Therefore, USCIS is notifying affected nationals of Honduras (or aliens with no nationality who last habitually resided in Honduras) that Form I–821 with Revision Date 11/05/04 will be accepted until further notice, and Form I–821 with Revision Date 7/30/04 will be accepted through January 3, 2005. All applicants are required to follow the same filing requirements as listed in the notice at 69 FR 64084 regardless of the version of the Form I–821 submitted.

DATES: This correction is effective November 17, 2004.


SUPPLEMENTARY INFORMATION:

Need for Correction

As published in the Federal Register on November 3, 2004 (69 FR 64084), the notice contains an error that is in need of correction.

Correction of Publication

Accordingly, the publication on November 3, 2004 (69 FR 64084), of the notice that was the subject of FR Doc. 04–24608 is corrected as follows:

1. On page 64086, beginning on the 8th line in the first column, the sentences “Please note that Form I–821 has been revised and only the new form with Revision Date 7/30/04 will be accepted. Submissions of older versions of Form I–821 will be rejected.” is corrected to read: “Please note that Form I–821 has been revised and the new form with Revision Date 11/05/04 will be accepted until further notice, and Form I–821 with Revision Date 7/30/04 will be accepted through January 3, 2005.”


Richard A. Sloan,
Director, Regulatory Management Division, U.S. Citizenship and Immigration Services.
[FR Doc. 04–25468 Filed 11–16–04; 8:45 am]