IOM CHANGE REQUEST/NOTICE (ICR/N) SEND TO IOM@FDA.HHS.GOV

DIRECTIONS

ORIGINATOR: COMPLETE SECTION 1 **REVIEWER:** COMPLETE SECTION 2

ICR Number
ICR- __ __ -__ __ __

SECTION 1	**1. Date:**
2. Title: ICR (Chapter/subchapter/Section/subsection/Item/subitem number) Year (YYYY) Title (or short description) e.g. **ICR 5.3.4.1Y2006 EVIDENCE DEVELOPMENT – IN PLANT PHOTOGRAPHS**	
3. Name:	**4. Organization:**
5. Phone:	**6. e-mail address:**
7. Reason for Change Request (Define in Detail):	
8. Recommended Solution[1]: **Priority: Urgent ☐ High ☐ Routine ☐**	
9. Attachments: Yes ☐or No ☐ (electronic attachments only)	

[1]If the change affects organizations outside originator's, additional review and concurrence is required by the Organization(s)

SECTION 2	**1. Date:**
2. Reviewing Official Name(s):	**3. Organization:**
4. Concur ☐ Forward ICR to other Reviewing Organizations (if applicable) and IOM@fda.hhs.gov 2. carbon copy (cc) Originator	
5. Do Not Concur ☐ **Give reason for nonconcurrence:**	
***6. Suggest a corrective action* (describe in detail):**	

Forward electronically to Originator and cc: IOM@fda.hhs.gov and other Reviewing Organizations

(**Reserved for HQ use only**)|c2005|

Concurred Yes ☐ No ☐ Signature _____Date ___/___/___

Comment:

Assigned To: _____ Priority - Urgent ☐ High ☐ Routine ☐

IOM Change Notice (ICN) No. _____Date ___/___/___

Solution to Problem:

Concurred/Signature _____Date ___/___/___