

DIR2006-04: Confidential Business Information Designation and Segregation Part 2: Previously Provided Test Data

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DIR2006-04 Applies to:

- 1. Open Applications:** *PCPA 2002* applies to all applications for which no decision to grant or deny the application has been made the on or before the day the *Act* comes into force.
 - ▶ CTD provided prior to PCPA coming into force
 - ◆ CBI designation as per DIR2006-03 upon submission
or
 - ◆ CBI designation retrospectively as per DIR2006-04

DIR2006-04 Applies to:

2. New Applications that cross-reference previously provided test data.

- ▶ PMRA must make accessible in the reading room when decision on application is reached.
- ▶ CBI will need to be addressed by the registrant whose data is cross-referenced.

DIR2006-04 Applies to

- 3. Existing Registrations:** Previously submitted CTD (Relevant to a decision) will be made available for inspection in the reading room following a final decision on which the public has been consulted under section 28:
- ▶ re-evaluation,
 - ▶ special review, or
 - ▶ application to register a major new use.

DIR2006-04 Steps

1. For the purpose of public inspection, PMRA automatically treats Data parts 2 & 3 as CBI for previously submitted data.
2. PMRA will send the current registrant a CBI Notice and a PMRA generated XML e-Index with a listing of all relevant data
3. Registrant to complete CBI designations for each record in the PMRA generated XML e-Index and return it to the PMRA.
4. PMRA will screen CBI designations
 - ▶ Send a second CBI Notice for pending issues.
5. PMRA will segregate approved designated CBI where required

Step 3. Content of CBI Designation Response

Return a separate CBI Designation Response for each CBI Notice.

1. Return completed XML e-index file to PMRA on CD or DVD
 - ▶ Clearly label For CBI Designation Response
2. Include a copy of the applicable CBI Notice

3.1 PMRA Generated XML e-Index

- ▶ Open with the most current version of the e-Index Builder Application → PMRA website.
- ▶ Allows editing of CBI field and comments field.
- ▶ CBI reference documents can be added by the registrant associated with each record in the XML e-Index
 - ◆ Must use copy row function of e-Index Builder Application
- ▶ Files that apply to many records or the entire list of data can be added.
 - ◆ e.g. DACO 0.8.12 – CBI Designation Authority

- ▶ **No Authority:** company does not have authority to designate CBI for this document
- ▶ **Yes:** I, on behalf of my company have authority and the entire document is CBI.
- ▶ **No:** I, on behalf of my company have authority and the document contains no CBI
- ▶ **Partial:** I, on behalf of my company have authority and the document does contain some CBI.
- ▶ **Request Copy:** I, on behalf of my company have authority but do not have record of this file and I request that the PMRA provide a copy to facilitate CBI designation.

No Authority

For each document claimed *No Authority*

- ▶ indicate in the Comments field the contact information identifying the company with the authority.

OR

- ▶ If the contact information applies to a large proportion of the documents listed, that information can be attached as a separate document in the PMRA Generated XML e-Index under DACO 0.8.12 – CBI Designation Authority

CBI Partial

For Each Document Claimed as CBI Partial

- ▶ Associate each document marked as partial with its CBI Reference document
 - ◆ use the copy row function of the e-Index Builder Application only

- ▶ Each CBI Reference Document:
 - ◆ Same format as CBI part 1 – DIR2006-03
 - identifies the title of the document to which the CBI pertains
 - indicates the CBI claimed
 - the reason for the CBI claims and
 - the coordinates (page and line) within the original document of the CBI.

Next Steps

- ▶ CBI Notices will be prioritized based on projected regulatory decision times.
 - ◆ PMRA has no intention of delaying decisions due to CBI.
- ▶ Once previously submitted test data has been designated/segregated as CBI it will be permanently protected as per PCPA 2002.

Key Points

- ▶ Transparency applies to all submissions that are open the day the PCPA 2002 comes into force.
 - ◆ Applicant needs to address CBI for all submissions that are still open the day the Act comes into force.
 - ◆ CBI must be addressed for all cross referenced test data.
- ▶ Re-evaluation, special review, major new use.
 - ◆ CBI needs to be addressed for data on existing products that is relevant to the decision.
- ▶ CBI can only be protected if it is designated as CBI and accepted as CBI as per PCPA 2002.