附件12

立卷审查要求（征求意见稿）意见反馈表

单位名称/专家名称： 联系人： 联系电话：

**1《医疗器械产品注册项目立卷审查要求（征求意见稿）》意见**

|  |  |  |  |
| --- | --- | --- | --- |
| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**2《医疗器械变更注册项目立卷审查要求（征求意见稿）》意见**

|  |  |  |  |
| --- | --- | --- | --- |
| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**3《医疗器械免临床目录对比立卷审查表（征求意见稿）》意见**

|  |  |  |  |
| --- | --- | --- | --- |
| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**4《医疗器械临床评价立卷审查表（征求意见稿）》意见**

|  |  |  |  |
| --- | --- | --- | --- |
| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**5《体外诊断试剂产品注册项目立卷审查要求（征求意见稿）》意见**

|  |  |  |  |
| --- | --- | --- | --- |
| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**6《体外诊断试剂变更注册项目立卷审查要求（征求意见稿）》意见**

|  |  |  |  |
| --- | --- | --- | --- |
| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**7《体外诊断试剂临床评价立卷审查表（非临床试验）（征求意见稿）》意见**

|  |  |  |  |
| --- | --- | --- | --- |
| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**8《体外诊断试剂临床评价立卷审查表（临床试验）（征求意见稿）》意见**

|  |  |  |  |
| --- | --- | --- | --- |
| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**9《医疗器械临床试验审批项目立卷审查要求（征求意见稿）》意见**

|  |  |  |  |
| --- | --- | --- | --- |
| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**10《 医疗器械延续注册项目立卷审查要求（征求意见稿）》意见**

|  |  |  |  |
| --- | --- | --- | --- |
| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**11《 体外诊断试剂延续注册项目立卷审查要求（征求意见稿）》意见**

|  |  |  |  |
| --- | --- | --- | --- |
| 涉及条款 | 原文内容 | 修改建议和意见 | 依据 |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |