00110332000479 8

上海市药品监督管理局
行政许可受理通知书

申请事项：第二类医疗器械产品注册（第二类医疗器械许可事项变更）

申请人：唯听助听器（上海）有限公司

产品名称：耳背式助听器

受理号：20-X110

你（单位）提出的上述行政许可申请收悉。经形式审查，根据《中华人民共和国行政许可法》第三十二条第一款第（五）项，我局决定予以受理。

我局将按照以下时限进行技术审评及行政审批，在规定工作日内作出是否准予行政许可的决定。

1、 受理（资料形式审查）5 个工作日

2、 技术审评 60 个工作日（如有与产品及生产变更有关的质量管理体系核查，另有 30 个工作日完成）

3、 行政审批 20 个工作日

4、 核发变更批件 10 个工作日

上海市药品监督管理局

2020 年 07 月 23 日

注：1、上海市药品监督管理局出具《行政许可受理通知书》的同时，将出具《行政许可项目缴费通知书》。

2、请按《行政许可项目缴费通知》的要求，到本机关行政服务中心收费窗口办理缴费手续。

3、申请人补充资料的时间、质量管理体系核查的时间、以及需要外聘专家审评、药械组合产品需与药品审评机构联合审评所需的时间，不计算在审评时限内。

（本文书一式两份，一份交申请人，一份留存归档）

Translated Version

Notice of acceptance of administrative license of Shanghai Drug Administration

Application: Registration of class II medical devices (change of licensing matters of category II medical devices)

Applicant: Hearing Aid (Shanghai) Co., Ltd.

Product Name: Behind-The-Ear Hearing Instruments

Acceptance No.: 20-x110

Your (unit) application for the above-mentioned administrative permission has been received and duly noted. After formal examination, according to the "Administrative Licensing Law of the People's Republic of China" Article thirty-two, paragraph 1(5) , the bureau decided to accept.

Our bureau will conduct technical review and administrative approval according to the following time limit, and make a decision on whether to grant administrative license within the specified working days.

1. 5working days for acceptance (review in the form of information)

2. 60 working days for technical review (another 30 working days for quality management system verification related to product and production changes, if any)

3. 20 working days for administrative examination and approval

4. 10 working days to verify release of change approval

Shanghai Drug Administration

2020 July 23, 2008

Note: 1. The Shanghai Drug Administration shall simultaneously issue the notice of acceptance of administrative license and the notice of payment for administrative license items.

2. Please go to the charging window of the Administrative Service Center of the local authority to pay fees according to the requirements of the "administrative license project payment notice".

3. The time required for the applicant to provide additional information, the time required for quality management system verification, the time required for external experts to review, and the time required for the joint review of drug and equipment combination products and drug evaluation institutions shall not be included in the review time limit.

(this document is in duplicate, one for the applicant and the other for filing)