March 3, 2021

To whom it may concern:

Company Name: Nichi-Iko Pharmaceutical Co., Ltd.
(Securities Code: 4541, Tokyo Stock Exchange)
Representative: Mr. Yuichi Tamura, President & CEO
Contact: Mr. Hiroshi Mogami, Head of Corporate Communication Department

Administrative Disposition to our Company

We would like to inform you with great humility that on March 3, 2021, we received an administrative disposition from Toyama Prefecture based on the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (the “Law”) of Japan.
As a pharmaceutical company that provides drugs contributing to the health of patients and their families, we take this administrative disposition very seriously, and we sincerely apologize to all stakeholders, including patients, their families, and medical personnel.

I. Overview of the Disposition:

1. Pharmaceutical Manufacturing License of the Toyama Plant 1

i. To: Toyama Plant 1 of Nichi-Iko Pharmaceutical Co., Ltd.
(Address: 205-1 Umesawa, Namerikawa City, Toyama Prefecture)
Scope: Pharmaceutical Manufacturing License (Registration No.: 16AZ000312)
The administrative disposition does not apply to the following operations.

a. Activities to inspect, maintain and improve the facilities and equipment
b. Use of the office buildings unrelated to manufacturing and shipping
c. Research and development work which do not directly use the manufacturing facilities
d. Customer service to address complaints and product returns
e. Operations related to quality control of the shipped products
f. Activities to properly store and manage products, raw materials and other materials
g. Activities to improve production control and quality control

ii. Date of issue: March 3, 2021 (Wed)

iii. Period: Suspension of business with Pharmaceutical Manufacturing License
(Total 32 days, from March 5, 2021(Fri) to April 5, 2021(Mon))

iv. Reasons:

a. The Toyama Plant 1 (“the Plant”) of Nichi-Iko has reprocessed its non-conforming products in the quality tests into conforming products, using different manufacturing methods from the ones defined in the manufacturing approval dossiers.

b. The Plant has not taken appropriate measures against the results of non-conformity in quality tests, etc.

c. The Manager for Drug Manufacturing at the Plant did not manage and supervise that the Plant properly performs production management and quality control.

The above-mentioned facts violated Clause 1, Article 8 referred by Clause 4, Article 17 of the Law as well as Article 96 of the Ordinance of the Enforcement of the Law (Ministry of Health and Welfare Ordinance No. 1, 1961).

2. Pharmaceutical Marketing License of Nichi-Iko Pharmaceutical Co., Ltd.

i. To: Nichi-Iko Pharmaceutical Co., Ltd.

(Address: 1-6-21, Sogawa, Toyama City, Toyama Prefecture)
Scope: Pharmaceutical Manufacturing and Distribution License (Registration No. for Class-1: 16A1X00009 and for Class-2: 16A2X00045)
However, the administrative disposition will not apply to operations related to safety management for post-marketing products and customer service for complaints and returned products.

ii. Date of issue: March 3, 2021 (Wed)

iii. Period: Suspension of business with Pharmaceutical Manufacturing and Distribution License (Total 24 days, from March 5, 2021(Fri) to March 28, 2021(Sun))

iv. Reasons:

a. Nichi-Iko ("the Company") has neglected to pay necessary consideration to properly manufacture and market its products, and the Company has not properly performed quality control on its products that it intended to produce and sell.
b. The Company has marketed its pharmaceutical products that the Plant produced using different manufacturing methods from the ones defined in the manufacturing approval dossiers.
c. The Drug Marketing Supervisor-General of the Company did not exercise necessary quality management work.

The above-mentioned facts violated Clause 13, Article 14 of the Law as well as Article 87 and Article 92 of the Ordinance of the Enforcement of the Law (Ministry of Health and Welfare Ordinance No. 1, 1961).

II. Background and Causes:

Upon the on-site inspection of the Plant by PMDA and the Toyama prefectural government, we immediately conducted an internal inspection and recognized certain issues with a portion of the Plant's manufacturing processes.
We determined that it was necessary to thoroughly and deeply investigate the matter, and hence established a comprehensive investigative project using external law firms and our Internal Audit Office. Since then, we have engaged in confirming facts, investigating root-causes and examining recurrence prevention measures by way of the project.
As our top priority, we simultaneously conducted a risk assessment of our products distributed on the market to clarify the safety and effectiveness of our products, referring to the matters indicated by PMDA and Toyama Prefecture.

As a result of this intensive and extensive investigation, we conducted voluntary recalls of our 75 products from April 2020 to mid-January 2021.
We have reported the investigation results etc. to PMDA and Toyama Prefecture as required. Upon receipt of the investigation results etc. from us, the administrative disposition was finally issued by Toyama Prefecture due to violations of law as described in the above 1. and 2.

III. Safety and Effectiveness of our Products on the Market

We truly regret the inconvenience that the voluntary recalls of our products have caused our related parties and stakeholders. As for products manufactured at the Plant and currently on the market, we have double-checked the manufacturing records and test records of all lots within their shelf life and confirmed no problems. We have also conducted quality tests of the reference samples (a sample of a batch of finished products stored for the purpose of being analyzed during the shelf life of the batch) for all lots and confirmed no problems regarding safety and effectiveness. We have not received any reports of health hazards related to this matter.

IV. Supply during the Administrative Disposition Period

The finished product inventories stored at our distribution centers (which completed their product release inspection before March 4, 2021) are able to be supplied to the market. Currently, we do our best to maintain a stable supply by securing a certain level of product inventories. However, it is possible to limit the supply of some products until all shipments are restarted.

V. Recurrence Prevention Measures and their Implementation

We have diligently made efforts to improve our business and operations, referring to the recurrence prevention measures recommended by the external lawyers and our Internal Audit Office. The implementation report and status of the recurrence prevention measures is set out in the Exhibit.

VI. Penalty on Board of Directors etc.

As we announced with our press release on July 13, 2020 “Penalty on the board of directors for voluntary recalls of our products”, we have penalized our board of directors and others for several voluntary recalls of our products manufactured at the Plant which caused such inconvenience, to ultimately identify where the responsibility lies. In addition

to that, we have decided to impose additional penalties upon receipt of this administrative disposition as follows.

1. Date of penalty: March 3, 2021
2. List of penalty:

Name and title of the board member	Penalty
Yuichi Tamura President and CEO Compliance	100% monthly salary cut for 3 months from March 2021
Takahiro Yoshikawa Representative Director and Deputy President Premium Quality, Procurement, and Biosimilar	50% monthly salary cut for 3 months from March 2021
Kenji Akane Deputy President CSR, ESG, and Business Creation	30% monthly salary cut for 3 months from March 2021
Noboru Inasaka Executive Vice President Strategy	30% monthly salary cut for 3 months from March 2021

VII. Outlook

We believe that the effect of this issue on our consolidated performance is immaterial. However, we take this administrative disposition very seriously, and we will strive to comply with Good Manufacturing Practice (GMP), Good Quality Practice (GQP) and other pharmaceutical regulations. As a company who provides pharmaceutical products, contributing to the health of patients and their families, we will work to ensure that the board of directors and all employees will work sincerely and seriously for recurrence prevention and make all efforts to restore trust in the Company.

Inquiries	Email: international-planning@nichiiko.co.jp

Exhibit

Recurrence Prevention Measures and Current Status

We have established and currently implement the following recurrence prevention measures as our business and operational improvement plans, based on the recommendations from the external lawyers and our Internal Audit Office.

I. Toyama Plant 1 (Pharmaceutical Manufacturing, GMP)

a. To clarify the standard operation procedures for management of out of specification (OOS) results and deviation cases (Completed on September 17, 2020)
   - One of the root-causes of the issues was a lack of concrete descriptions in the standard operation procedures. Given that, we clearly and concretely redefined the said procedures to prevent non-conforming products from being shipped and improperly processed.

b. To tighten management of batch production records and test records
   - We upgraded our management methods for maintaining test records to be stricter to prevent products from being incorrectly retested and improperly reprocessed.
   - We plan to introduce the Manufacturing Execution System (MES) to promote data integrity and to prevent products from being improperly reprocessed. Before MES, we will introduce the Supervisory Control And Data Acquisition (SCADA) system to gather and manage data from all manufacturing machines and equipment (to be completed on September, 2021). The automatic synchronization between manufacturing orders and records for all products and MES will be completed in 2023.
   - We defined reporting lines to our newly opened internal GMP Audit Office and established a new monitoring system by the said audit office so as not to process products improperly in the case of inspection failure (to be completed March 31, 2021).

c. To restructure our GMP organization (Completed on July 31, 2020)
   - We newly appointed our company's Manager for Drug Manufacture and the deviation manager, who have capabilities, duties and authorities to properly manage and supervise in accordance with GMP.

d. To educate and train continuously and exhaustively our employees on GMP (On-going measures)
   - We drastically reviewed and renewed our GMP employee education and trainings to

conform to GMP. We also introduced new GMP education and training programs etc. provided by our internal GMP Audit Office and external experts etc., aiming at continuous and thorough GMP education.

e. To strengthen authorities of quality control sections and Quality Assurance departments (Completed on July 31, 2020)
   - We reorganized and allocated employees to strengthen the authority of our quality control sections, so that the quality control arms properly function in our organization, reflecting our practical day-to-day operations.

f. To establish the Stability Monitoring Group and audit scheme by the GMP Audit Office
   - We newly established the Stability Monitoring Group dedicated for the well-planned implementation of stability studies, and we expanded its functions with more staffing and enhanced facilities and equipment. As of the end of December 2020, we have allocated an additional 24 employees and enhanced our facilities and equipment, and we currently are continuing to expand staff and facilities.
   - We set up new structures for the internal GMP Audit Office etc. to monitor and supervise the implementation status of stability studies as required, in order to prevent stability studies from being skipped. (Completed on July 31, 2020)

II. Nichi-Iko Head Office (Pharmaceutical Marketing, GQP)

a. To review and thoroughly execute GMP audit procedures by Quality Assurance & Pharmacovigilance Division (Completed on October 1, 2020)
   - We fully reviewed GMP audit methods and procedures, so that we are able to properly exercise GMP audits and supervise the functions of our plants as a pharmaceutical manufacturer and distributor.

b. To replace the Drug Marketing Supervisor-General (Completed on July 31, 2020)
   - The then Drug Marketing Supervisor-General who was involved in the improper relief processing was, at the same time, our company's Manager for Drug Manufacture. We took this very seriously and replaced the Manager for Drug Manufacture with an appropriate person.

III. Strengthening of Internal Audit and Supervising Function

a. To strengthen the internal audit structure by the GMP Audit Office
   - We newly created the GMP Audit Office internally, in order to properly fulfill certain audit and supervising functions, and we established a new monitoring structure to

prevent improper production and testing from reoccurring. (Completed on October 1, 2020)

- We also constructed a collaborative structure with respect to audits by the GMP Audit Office and audits by QA & Pharmacovigilance Division, so that both teams are able to fully exercise their functions by defining the roles of divisions as well as imposing a checks-and-balances system between the two teams. (Completed on January 1, 2021)

b. To reintroduce the whistle-blowing system (Completed on July 15, 2020)

- We thoroughly notified our employees of the existence of the whistle-blowing system and promoted effective use of the system, so that issues like this can be properly reported through the whistle-blowing system.

IV. Management and Organization in General

a. To reform our corporate culture (On-going measures)

- We formulated “New Quality Policies” consisting of five “Quality Principles” including law compliance, quality improvement and maintenance, information sharing, education and transfer of techniques, and stable supply. All of our divisions and departments have set up their objectives based on the quality policies and regularly report their activities to management.

b. To redistribute authorities and responsibilities among the board members (Completed on July 13, 2020)

- The fact that one executive director was responsible for both stable supply and quality was an indirect cause of the issues. After reflecting on this, we nominated an executive director to be in charge of quality (Mr. Yoshikawa, Deputy President) and we redistributed authorities among the board members and executive officers (particularly with respect to the head of the Quality Control Division)

c. To conduct compliance trainings for the board members (On-going measures)

- We conducted compliance trainings for the board members on July 13, 2020 and August 17, 2020. Ever since then, we have held compliance trainings for the management in the monthly board meetings and weekly management meetings as necessary.

d. To establish and maintain reasonable production planning and system (On-going measures)

- A lack of staffing and facilities for required tests corresponding to our production plans was the main root-cause of the issues underlying this matter. Hence, we are

proceeding with reasonable production planning, actual production activities and production management accordingly.

e. To review formulation designs and strengthen the formulation reassessment system (On-going measures)
   - We created quality improvement plans for our products which tend to fail at product release inspections. Through the quality improvement plans, we examine with an eye toward updating our manufacturing methods and to upgrade our approval standards, to promote the production of conforming products.

f. To clarify responsibilities regarding the issues and penalize responsible personnel
   - We penalized the responsible personnel as we stated in the above-mentioned VI.